

EPA Jacket 100-1270

Vol.1

Recommendation of Division Directors

Negotiated Due Dates

Decision #: D452137	Registration #: 100-904	Petition #: ---
D452134	100-1270	---
D452138	---	1E7904
<input checked="" type="checkbox"/> See page 2 for additional registration entries		
Chemical Name: emamectin benzoate		
Fee Category: R170, R230		PRIA Decision Time Frame: 15 months
Submitted by: Thomas Harris		Branch: OCSP/OPP/RD Date: 10/23/2012
Company: Syngenta Crop Protection		
Original PRIA Due Date: 10/25/2012		Proposed New PRIA Due Date: 12/20/2012
Previous Negotiated Due Dates: 10/25/2012		
Is the "Fix" in-house? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> n/a If not, date "Fix" expected:		
Negotiated Due Date Reason:		
Additional Data Required	<input type="checkbox"/> Product Chemistry <input type="checkbox"/> Toxicology <input type="checkbox"/> Acute Tox <input type="checkbox"/> Environmental <input type="checkbox"/> Efficacy <input type="checkbox"/> Ecological <input type="checkbox"/> Residue <input type="checkbox"/> Other	
Data Deficiencies	<input type="checkbox"/> Product Chemistry <input type="checkbox"/> Acute Tox <input type="checkbox"/> Efficacy <input type="checkbox"/> Residue <input type="checkbox"/> Toxicology <input type="checkbox"/> Environmental <input type="checkbox"/> Ecological <input type="checkbox"/> Labeling <input type="checkbox"/> Other <input type="checkbox"/> Not Submitted	
Late Risk Assessment	<input type="checkbox"/> Human Health <input type="checkbox"/> Ecological	
Interim Consideration	<input type="checkbox"/> Agency Initiated <input type="checkbox"/> Registrant Initiated	
<input type="checkbox"/> CSF	<input type="checkbox"/> Public Process	<input type="checkbox"/> Risk Issues Environmental <input type="checkbox"/> Risk Issues Human Health
<input type="checkbox"/> Impurities Review	<input type="checkbox"/> Label	<input type="checkbox"/> Administrative-FR Notice <input checked="" type="checkbox"/> Other – Comment Field
Summary of Deficiency Type(s): <input type="checkbox"/> Not Submitted (N) <input type="checkbox"/> Deficiencies (D) Product Chemistry: <input type="checkbox"/> Acute Tox: <input type="checkbox"/> Efficacy: <input type="checkbox"/> Labeling: <input type="checkbox"/> Ecological Data: <input type="checkbox"/> Other (describe): <input type="checkbox"/>		
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates): Phone discussions and email. Copy of Syngenta 10/23/12, 5:35 pm email stating concurrence is attached (.pdf).		
"75 Day" Letter sent? <input type="checkbox"/> Yes, Date sent <input type="checkbox"/> No and reason for none? <i>Add comments on page 2</i>		
Rationale for Proposed Due Date: address issues in risk assessment raised by OGC		
Registrant notified that this is the last negotiation? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Applicable		
Approve: <input type="checkbox"/>		Disapprove: <input type="checkbox"/>
If disapproved, action to be taken:		
OD or DOD Signature:		Date:

Decision #: D449308	Registration #: 100-RURR	Petition #:

Issue(s) (describe in detail):

PREVIOUSLY: 100-RURR ornamentals had been negotiated from original PRIA date 9/8/12 to negotiated 10/25/12 to match cucurbits since the two uses are being analyzed together (but had come in slightly different times hence the difference in original due dates).

Purpose of this negotiation is to allow for re-work on HED risk assessment to address issues raised by OGC during review of FR final rule. HED will rewrite risk assessment, then RD will rewrite FR final rule, then both will be sent through OGC for concurrence again.

FYI: cucurbits is R170, ornamentals is R230

Comment(s):



Syngenta agrees to new PRIA 12/20/12: - Emamectin cucurbits & commercial use ornamentals

carolyn.brinkley to: Thomas Harris

Cc: tom.parshley

10/23/2012 05:35 PM

From: <carolyn.brinkley@syngenta.com>
To: Thomas Harris/DC/USEPA/US@EPA
Cc: <tom.parshley@syngenta.com>

Hi Tom,

In response to your attached e-mail request to Tom Parshley and me, I'm sending you our reply to your request to change the PRIA date for the pending registration actions for emamectin . Specifics follow.

I. EXTENSION OF PRIA DATE for PENDING EMAMECTIN ACTIONS

This e-mail is to inform you that Syngenta Crop Protection LLC agrees to the extension of

the October 25, 2012 PRIA date to December 20, 2012 for the following emamectin actions:

A. CUCURBITS

a. Tolerance Petition cucurbits (Crop Group 9): PP#: 1E7904

i. Associated applications for
registration

1. Proclaim® Insecticide (EPA Reg. No. 100-904): add directions for use for cucurbits (Crop Group 9)

2. Emamectin Benzoate Technical II (EPA Reg. No. 100-1270): add cucurbits approved crops list

B. OUTDOOR COMMERCIAL USE -- ORNAMENTALS PRODUCTION

a. Application for New Product Registration / New Emamectin Use

i. New Product: Enfold™
(100-RURR). ----- same formula as Proclaim Insecticide -

100-904 ----- New Use: This is the first use of emamectin for
ornamentals

Best regards,

Carolyn F. Brinkley, Sr. Regulatory Product Manager / NAFTA Insecticides (
emamectin, abamectin, cyromazine, profenofos, pymetrozine)

Syngenta Crop Protection

From: harris.thomas@epamail.epa.gov [mailto:harris.thomas@epamail.epa.gov]
Sent: Monday, October 22, 2012 5:57 PM
To: Brinkley Carolyn USGR
Cc: Parshley Tom USGR
Subject: RE: emamectin - request to extend due date for new uses on cucurbits and ornamentals

Just checking in. Actions are currently due Thursday (10/25) so I need to try to get paperwork filed at my
end by Tuesday 10/23.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit <http://www.epa.gov/pesticides>

—10/19/2012 02:24:34 PM---Hi Tom, will get back to you in a couple of days. From:
harris.thomas@epamail.epa.gov [mailto:harris

From: <carolyn.brinkley@syngenta.com>
To: Thomas Harris/DC/USEPA/US@EPA
Cc: <tom.parshley@syngenta.com>
Date: 10/19/2012 02:24 PM
Subject: RE: emamectin - request to extend due date for new uses on cucurbits and ornamentals

Hi Tom, will get back to you in a couple of days.

From: harris.thomas@epamail.epa.gov [mailto:harris.thomas@epamail.epa.gov]
Sent: Thursday, October 18, 2012 3:54 PM
To: Brinkley Carolyn USGR; Parshley Tom USGR
Cc: Hebert.John@epamail.epa.gov; Laws.Meredith@epamail.epa.gov; Madden.Barbara@epamail.epa.gov; Ertman.Andrew@epamail.epa.gov
Subject: emamectin - request to extend due date for new uses on cucurbits and ornamentals

Carolyn, Tom:

We are wrapping up two pending new use PRIA actions for emamectin: cucurbits crop group 9 (100-1270, 100-904, 1E7904) and outdoor, commercial ornamental production (100-RURR). The PRIA due dates for all actions are 10/25/12. Unfortunately, we've hit a snag and need to extend the due dates.

As you are aware from your own assessment of these new uses, we are running very close to the limit of the risk cup. The initial OPP risk assessment using our default conservative assumptions did not pass. After several refinements including both percent crop treated and anticipated residues the new uses now pass at 98% of the risk cup. However, in reviewing the current human health risk assessment and draft FR final rule our lawyers have raised several objections. After some discussion we have found a way to satisfy their concerns but this requires rework of both the risk assessment and the resulting FR final rule. We still anticipate that the uses will be approved but need additional time to make these revisions.

To that end, we are requesting to extend the PRIA due dates for all actions from 10/25/12 to 12/20/12. Even with the upcoming holidays that should provide sufficient time for the revisions to the risk assessment and publication of the FR final rule. Please note that since both cucurbit and ornamentals uses are addressed in the same reviews we need to extend due dates for both new uses.

Please respond to this email letting me know if you agree with the negotiated due date of 12/20/12. Thank you.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit <http://www.epa.gov/pesticides>

This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately.

and delete the original and any copies. Any use of the message by you is prohibited.

This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.



Recommendation of Division Directors Negotiated Due Dates has been completed by William Jordan.

Workflow Messenger to: William Jordan, Thomas Harris
Sent by: William Jordan

10/24/2012 02:11 PM

Recommendation of Division Directors Negotiated Due Dates has been completed by William Jordan.

Author: Thomas Harris
Chemical: emamectin benzoate
Form Date: 10/23/2012
Decision #: D452137
D452134
D452138
Registration #: 100-904
100-1270

Petition #: ---

1E7904
Original PRIA Due Date: 10/25/2012
Previous Negotiated Due Dates: 10/25/2012, , ,
Proposed New PRIA Due Date: 12/20/2012

Click on this link to access this form:

<https://webforms.epa.gov/webforms/webformsadmin.nsf/formOpen?OpenAgent&UNID=7D42C6C3F3DFB93C85257AA000730F15&USERDB=webforms/webformsapp.nsf>

Click on this link to access all your forms:

<https://webforms.epa.gov/webforms/webformsapp.nsf>

August 1, 2011

John,

These are section 3 label amendments (EPA Reg # 100-1270 (technical), D452134 & 100-904, D452137) submitted with an IR-4 petition (PP# 1E7904) - for use of emamectin benzoate on the cucurbit vegetable crop group 9. The Minor Use Team will send data into review for this petition to HED for the human health risk assessments and EFED for the drinking water estimates.

not back
X
EFED requests that the Product Management Team send the section 3 label amendments into review as well in order for EFED to conduct the ecological risk.

The MUT has created a docket for this action and have requested that you be given rights to the docket in order for the PM team to include the Notice Pesticide Products; Registration Applications in this docket. **The docket # is EPA-HQ-OPP-2011-0665.**

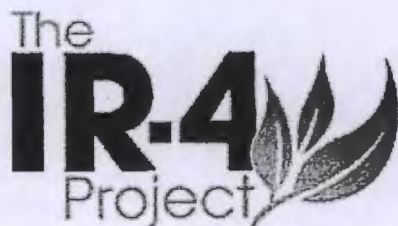
Andy Ertman on the Minor Use Team has been assigned this action. If you think there is a need for a team meeting with HED and EFED to discuss any issues please let Laura or Barbara know and we will schedule one. Otherwise we will wait to hear from the science divisions to determine if they want a meeting before we schedule anything.

Please let me know if you need any additional information.

Thanks

Andy Ertman
308-9367

*Also see 100-904 & 1E7904
for additional details on this action.*



IR-4 Project Headquarters
 Rutgers, The State University of New Jersey
 500 College Road East, Suite 201W
 Princeton, NJ 08540
 732-932.9575 fax: 609-514-2612

July 13, 2011

Ms. Barbara Madden
 IR-4 Minor Use Officer
 USEPA OPP/Doc Proc Desk (REGFEE)
 Room S-4900
 One Potomac Yard
 2777 S. Crystal Drive
 Arlington, VA 22202

Dear Barbara:

RE: **Emamectin Benzoate**
PROCLAIM[®] Insecticide, EPA Reg. No. 100-904

Emamectin (a mixture of a minimum of 90% 4'-epi-methylamino-4'-deoxyavermectin B_{1a} and maximum of 10% 4'-epi-methylamino-4'-deoxyavermectin B_{1b}) and its metabolites 8,9-isomer of the B_{1a} and B_{1b} component of the parent (8,9-ZMA), or 4'-deoxy-4'-epi-amino-avermectin B_{1a} and 4'-deoxy-4'-epi-amino-avermectin B_{1b}; 4'-deoxy-4'-epi-amino avermectin B_{1a}(AB_{1a}); 4'-deoxy-4'-epi-(N-formyl-N-methyl)amino-avermectin (MFB_{1a}); and 4'-deoxy-4'-epi-(N-formyl)amino-avermectin B_{1a}(FAB_{1a})

New Uses in tolerance proposal: Crops in VEGETABLE, CUCURBIT, GROUP 9

Commodity or Crop Group	IR-4 PR No.	Support for Tolerance Proposal
Cucumber	06987	Volume 2
Squash	08939	Volume 3
Cantaloupe	08940	Volume 4

Review; 3 final reports

FEE CATEGORY: R-170

REGISTRATION FEE: 3 X \$59,976= \$179,928 (See IR-4 Exemption Request below)

ELECTRONIC SUBMISSION TO FOLLOW

The undersigned, Raymond C. Leonard, Associate Coordinator, Interregional Research Project No. 4, State Agricultural Experiment Station, Rutgers, The State University of New Jersey, Princeton, New Jersey 08540, on behalf of the IR-4 Project and the Agricultural Experiment Stations of Oklahoma, California, Arizona, Tennessee, North Carolina, Georgia and Florida (cucumber); Oklahoma, Puerto Rico, California, North Carolina, Georgia, Florida, Tennessee and Indiana (squash); and Oklahoma, Puerto Rico, California, Arizona, North Carolina, Georgia, Florida, Tennessee and Indiana (cantaloupe) submit the present petition pursuant to

Section 408(e) of the Federal Food, Drug and Cosmetic Act, as amended, with respect to the pesticide chemical, emamectin (40 CFR 180.505).

We request that this petition be reviewed under the Pesticide Registration Improvement Act and that EPA should exempt the registration fee for review of these uses.

List of Studies Submitted in Support of Proposed Tolerance for emamectin:

Volume No.	Volume Title
1	Administrative Volume (Petition Proposing a Crop Group Tolerance for EMAMECTIN BENZOATE in or on Crops in VEGETABLE, CUCURBIT, GROUP 9
2	Emamectin Benzoate: Magnitude of the Residue on Cucumber
3	Emamectin Benzoate: Magnitude of the Residue on Squash
4	Emamectin Benzoate: Magnitude of the Residue on Cantaloupe

48539701
48539702
48539703

For neurotoxicity and immunotoxicity studies:

According to the enclosed letter from Syngenta Crop Protection, LLC dated May 26, 2011, the required study for subchronic neurotoxicity (OPPTS Guideline 870.6200) was submitted to EPA on December 18, 1992 (MRID No. 42743628) and the required study for acute neurotoxicity (OPPTS Guideline 870.6200) was submitted on December 21, 1992 (MRID No. 42743618). The immunotoxicity study (OPPTS Guideline 870.7800) is planned to be initiated in September 2011 with an April 2012 EPA submission date. The results of the study are not expected to impact the human health risk assessment.

IR-4 is also submitting the following that has been provided by Syngenta Crop Protection:

NOTICE OF FILING for the use of emamectin in or on the raw agricultural commodities within VEGETABLE, CUCURBIT, GROUP 9

Emamectin benzoate technical II:

- EPA Form 8570-1 Registration Package Form for emamectin benzoate technical II
- EPA Form 8570-34 Certification with Respect to Citation of Data for emamectin benzoate technical II
- EPA Form 8570-35 emamectin benzoate technical II Data Matrix both private and public versions
- emamectin benzoate technical II (5 copies+ one with highlighted changes)

PROCLAIM

- EPA Form 8570-1 Registration Package Form for PROCLAIM
- EPA Form 8570-27 Formulators Exemption Statement Formulators Exemption Statement.
- EPA Form 8570-34 Certification with Respect to Citation of Data for PROCLAIM
- EPA Form 8570-35 PROCLAIM Data Matrix both private and public versions
- PROCLAIM label (5 copies+ one with highlighted changes)

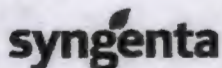
Please contact John Abbott, Syngenta, Tel. No. (800) 334- 9481 or by e-mail at john.abbott@syngenta.com if necessary.

Yours very truly,
Interregional Research Project No. 4
Petitioner

Per Raymond C. Leonard

Raymond C. Leonard
Associate Coordinator
IR-4 Project Headquarters
500 College Road East, Suite 201W
Princeton, NJ 08540
Email: leonard@aesop.rutgers.edu

Cc: IR-4 Regional Field Coordinators (Uploaded letter & administrative volume); Keith Dorschner (IR-4, letter only), Ken Samoil (IR-4, letter only), Debbie Carpenter (IR-4, letter only), Dan Kunkel, (IR-4, letter only)
John Abbot, Syngenta (All: paper & electronic); Dirk Drost (Letter)



Regulatory Affairs
P.O. Box 18300
Greensboro, NC 27419-8300

Telephone: (336) 632-7074
Fax: (336) 632-5688

May 26, 2011
Document Processing Desk (IR-4)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive – Room S-4900
Arlington, VA 22202

Attention: Ms. Barbara Madden:

SUBJECT: Enamectin benzoate Petition for a Tolerance as End-Use Product Proclaim Insecticide (EPA Reg. No. 100-904) and as Enamectin benzoate Technical II (100-1270) Status on Immunotoxicity and Neurotoxicity Studies

Dear Ms. Madden:

Syngenta Crop Protection, LLC would like to provide an update on the status of the required guideline studies (immunotoxicity and neurotoxicity) for emamectin benzoate. The acute neurotoxicity study was completed and submitted on December 21, 1992 (MRID No. 42743618). The subchronic neurotoxicity study was completed and submitted on December 18, 1992 (MRID No. 42743628). The immunotoxicity study is planned to be initiated September 2011 and submitted April 2012.

As stated in the EPA Human Health Risk Assessment dated July 31, 2008 (Decision No. 384481), Section 3.2.1, FQPA Considerations, Adequacy of the Toxicity Database, "the toxicology data base for emamectin is complete and sufficient to determine human hazard and FQPA assessments," and "at this time, the acute and chronic RfD's are 0.00025 mg/kg/day and 0.000075 mg/kg/day, respectively; and a database uncertainty factor is not necessary to account for a lack of an immunotoxicity study."

If you have any questions or comments, please contact me at 336-632-7074 or by email at john.abbott@syngenta.com. Thank you for your assistance.

Sincerely,

John D. Abbott, Ph.D., CPH
Team Leader
NAFTA Regulatory Affairs-Herbicides



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 25, 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

IR-4 PROJECT HEADQUARTERS
500 COLLEGE EAST, SUITE 201W
PO.BOX : PRINCETON, NEW JERSEY 08540

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 15-JUL-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Tolerance Petition

S: 899712

Regulatory Type: Tolerance Petition

Application Type: New Registration

Company: 959857 Interregional Research Project No. 4

Risk Mgr: Registration Division, Risk Management Team 5

Petition #: 1E7904

Petition Type: E - Minor Use (IR-4/State)

Resubmission: ☐ Yes ☒ No

Fee For Service: ☐ Yes ☒ No

Billable: ☒ Yes ☐ No

Fee Waived: ☐ Yes ☒ No

Fee:

Print Letter

Enter More Information

Tracking

Application Date: 13-Jul-2011

Front End Date: 18-Jul-2011

FFS Due Date:

OPP Target Date:

OPP Rec'd Date: 15-Jul-2011

Risk Manager Send Date: 18-Jul-2011

Negotiated Due Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

emamectin benzoate in/on crops in vegetable, cucurbit, group 9

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

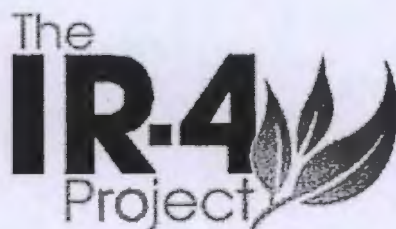
Receipt Content

Other

notice of filing

View/Edit

16



IR-4 Project Headquarters
 Rutgers, The State University of New Jersey
 500 College Road East, Suite 201W
 Princeton, NJ 08540
 732.932.9575 fax: 609-514-2612

July 13, 2011

Ms. Barbara Madden
 IR-4 Minor Use Officer
 USEPA OPP/Doc Proc Desk (REGFEE)
 Room S-4900
 One Potomac Yard
 2777 S. Crystal Drive
 Arlington, VA 22202

Dear Barbara:

RE: **Emamectin Benzoate**
PROCLAIM® Insecticide, EPA Reg. No. 100-904

Emamectin (a mixture of a minimum of 90% 4'-epi-methylamino-4'-deoxyavermectin B_{1a} and maximum of 10% 4'-epi-methylamino-4'-deoxyavermectin B_{1b}) and its metabolites 8,9-isomer of the B_{1a} and B_{1b} component of the parent (8,9-ZMA), or 4'-deoxy-4'-epi-amino-avermectin B_{1a} and 4'-deoxy-4'-epi-amino-avermectin B_{1b}; 4'-deoxy-4'-epi-amino avermectin B_{1a}(AB_{1a}); 4'-deoxy-4'-epi-(N-formyl-N-methyl)amino-avermectin (MFB_{1a}); and 4'-deoxy-4'-epi-(N-formyl)amino-avermectin B_{1a}(FAB_{1a})

New Uses in tolerance proposal: Crops in VEGETABLE, CUCURBIT, GROUP 9

Commodity or Crop Group	IR-4 PR No.	Support for Tolerance Proposal
Cucumber	06987	Volume 2
Squash	08939	Volume 3
Cantaloupe	08940	Volume 4

Review; 3 final reports

FEE CATEGORY: R-170

REGISTRATION FEE: 3 X \$59,976= \$179,928 (See IR-4 Exemption Request below)

ELECTRONIC SUBMISSION TO FOLLOW

The undersigned, Raymond C. Leonard, Associate Coordinator, Interregional Research Project No. 4, State Agricultural Experiment Station, Rutgers, The State University of New Jersey, Princeton, New Jersey 08540, on behalf of the IR-4 Project and the Agricultural Experiment Stations of Oklahoma, California, Arizona, Tennessee, North Carolina, Georgia and Florida (cucumber); Oklahoma, Puerto Rico, California, North Carolina, Georgia, Florida, Tennessee and Indiana (squash); and Oklahoma, Puerto Rico, California, Arizona, North Carolina, Georgia, Florida, Tennessee and Indiana (cantaloupe) submit the present petition pursuant to

Section 408(e) of the Federal Food, Drug and Cosmetic Act, as amended, with respect to the pesticide chemical, emamectin (40 CFR 180.505).

We request that this petition be reviewed under the Pesticide Registration Improvement Act and that EPA should exempt the registration fee for review of these uses.

List of Studies Submitted in Support of Proposed Tolerance for emamectin:

Volume No.	Volume Title
1	Administrative Volume (Petition Proposing a Crop Group Tolerance for EMAMECTIN BENZOATE in or on Crops in VEGETABLE, CUCURBIT, GROUP 9
2	Emamectin Benzoate: Magnitude of the Residue on Cucumber
3	Emamectin Benzoate: Magnitude of the Residue on Squash
4	Emamectin Benzoate: Magnitude of the Residue on Cantaloupe

For neurotoxicity and immunotoxicity studies:

According to the enclosed letter from Syngenta Crop Protection, LLC dated May 26, 2011, the required study for subchronic neurotoxicity (OPPTS Guideline 870.6200) was submitted to EPA on December 18, 1992 (MRID No. 42743628) and the required study for acute neurotoxicity (OPPTS Guideline 870.6200) was submitted on December 21, 1992 (MRID No. 42743618). The immunotoxicity study (OPPTS Guideline 870.7800) is planned to be initiated in September 2011 with an April 2012 EPA submission date. The results of the study are not expected to impact the human health risk assessment.

IR-4 is also submitting the following that has been provided by Syngenta Crop Protection:

NOTICE OF FILING for the use of emamectin in or on the raw agricultural commodities within VEGETABLE, CUCURBIT, GROUP 9

Emamectin benzoate technical II:

- EPA Form 8570-1 Registration Package Form for emamectin benzoate technical II
- EPA Form 8570-34 Certification with Respect to Citation of Data for emamectin benzoate technical II
- EPA Form 8570-35 emamectin benzoate technical II Data Matrix both private and public versions
- emamectin benzoate technical II (5 copies+ one with highlighted changes)

PROCLAIM

- EPA Form 8570-1 Registration Package Form for PROCLAIM
- EPA Form 8570-27 Formulators Exemption Statement Formulators Exemption Statement.
- EPA Form 8570-34 Certification with Respect to Citation of Data for PROCLAIM
- EPA Form 8570-35 PROCLAIM Data Matrix both private and public versions
- PROCLAIM label (5 copies+ one with highlighted changes)

Please contact John Abbott, Syngenta, Tel. No. (800) 334- 9481 or by e-mail at john.abbott@syngenta.com if necessary.

Yours very truly,
Interregional Research Project No. 4
Petitioner

Per Raymond C. Leonard

Raymond C. Leonard
Associate Coordinator
IR-4 Project Headquarters
500 College Road East, Suite 201W
Princeton, NJ 08540
Email: leonard@aesop.rutgers.edu

Cc: IR-4 Regional Field Coordinators (Uploaded letter & administrative volume); Keith Dorschner (IR-4, letter only), Ken Samoil (IR-4, letter only), Debbie Carpenter (IR-4, letter only), Dan Kunkel, (IR-4, letter only)
John Abbot, Syngenta (All: paper & electronic); Dirk Drost (Letter)

21-Day Screen of Amendment
(Completed by Contractor)

21-day Expires on 8-5-11

Document Part Of: 100 - 1270
MRID, If Any: 485 397

Content Screen: Recommended to
Pass/Fail

86-5 Review: Passed/Failed/NA

Overall Status: Pass/Fail

Document returned to:

Stephen Schauble

PM 7

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 7-15-11

Experts In-Processing Signature: M F Harrington Date 7-20-11 Fee Paid: Yes

Division management contacted on issues No Yes Date

EPA Reg. Number: <u>100 - 1270</u>		EPA Receipt Date: <u>7-15-11</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)					X
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
		X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		X
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

Studies passed Rb-S Review

Jacket associated w/ 1E7904 and 100-904

JB

07/27/11

MRID: 485397

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbpd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 20, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-452134
EPA File Symbol or Registration Number: 100-1270
Product Name: EMAMECTIN BENZOATE TECHNICAL II
EPA Receipt Date: 15-Jul-2011
EPA Company Number: 100
Company Name: SYNGENTA CROP PROTECTION, LLC

BUNNIE KONAT
SYNGENTA CROP PROTECTION, LLC
D/B/A SYNGENTA CROP PROTECTION, INC.
PO Box 18300
GREENSBORO, NC 27419-8300

SUBJECT: Receipt of Amendment and IR-4 Fee Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application for amendment and IR-4 fee waiver request. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R170.3
NEW USE;EACH ADDITIONAL NEW FOOD USE;THREE NEW USES;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If the determination indicates that payment is due, you will receive instructions for submitting payment at that time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman, at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "m. j. [unclear]".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{8997021~

This package includes the following

☐ New Registration

☒ Amendment

☒ Studies? ☒ Fee Waiver?

☐ volpay % Reduction: IR4-

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr.

7

Receipt No.

S-

899702

EPA File Symbol/Reg. No.

100-1270

Pin-Punch Date:

7/15/2011

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

R170

Granted:

R170.3

Amount Due: \$

179,928

Parent/Child Decisions:

5899712 / 1E7904
5899704 / 100-904

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: JPH

Date: 7/20/11

Remarks:

Receipt for Section 3

S: 899702

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☒ Yes ☐ No

Company: 100 SYNGENTA CROP PROTECTION, LLC

V

Risk Manager: Registration Division, Risk Management Team 7

Product #: 100-1270

Product Name: EMAMECTIN BENZOATE TECHNICAL II

Override#:

Me Too

Section3: 100-895

Me Too

Product Name: ABAMECTIN TECHNICAL

Application Date: 13-Jul-2011

id

OPP Rec'd Date: 15-Jul-2011

id

Front End Date: 18-Jul-2011

id

Risk Manager Send Date:

id

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

is in support of the IR-4 petition for active ingredient Emamectin Benzoate

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Study

Paper Label

View/Edit

New Ingredient

Request Date:

New Ingredient

Received Date:



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 100-1270	2. EPA Product Manager Thomas Harris	3. Proposed Classification <input type="checkbox"/> None <input checked="" type="checkbox"/> Restricted
4. Company/Product (Name) Emamectin Benzoate Technical II	PM# IRB	
5. Name and Address of Applicant (Include ZIP Code) Syngenta Crop Protection, LLC P. O. Box 18300 Greensboro, NC 27419 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.).

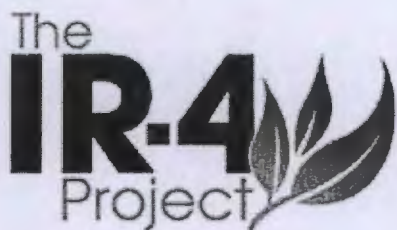
This registration application is in support of the IR-4 petition for active ingredient emamectin benzoate on cucurbit vegetables crop group 9.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
*Certification must be submitted				<input type="checkbox"/> Plastic	
	If "Yes" Unit Packaging wgt.	No. per Container	If "Yes" Unit Packaging wgt.	<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Other <u>Pressure Sensitive</u> <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name John D. Abbott, Ph. D., CPH		Title NAFTA Insecticides Team Lead		Telephone No. (Include Area Code) 336-632-7074	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title NAFTA Insecticides Team Lead			
4. Typed Name John D. Abbott		5. Date April 15, 2011			



IR-4 Project Headquarters
Rutgers, The State University of New Jersey
500 College Road East, Suite 201W
Princeton, NJ 08540
732-932-9575 fax: 609-514-2612

July 13, 2011

Ms. Barbara Madden
IR-4 Minor Use Officer
USEPA OPP/Doc Proc Desk (REGFEE)
Room S-4900
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Dear Barbara:

RE: **Emamectin Benzoate**
PROCLAIM® Insecticide, EPA Reg. No. 100-904

Emamectin (a mixture of a minimum of 90% 4'-epi-methylamino-4'-deoxyavermectin B_{1a} and maximum of 10% 4'-epi-methylamino-4'-deoxyavermectin B_{1b}) and its metabolites 8,9-isomer of the B_{1a} and B_{1b} component of the parent (8,9-ZMA), or 4'-deoxy-4'-epi-amino-avermectin B_{1a} and 4'-deoxy-4'-epi-amino-avermectin B_{1b}; 4'-deoxy-4'-epi-amino avermectin B_{1a}(AB_{1a}); 4'-deoxy-4'-epi-(N-formyl-N-methyl)amino-avermectin (MFB_{1a}); and 4'-deoxy-4'-epi-(N-formyl)amino-avermectin B_{1a}(FAB_{1a})

New Uses in tolerance proposal: Crops in VEGETABLE, CUCURBIT, GROUP 9

Commodity or Crop Group	IR-4 PR No.	Support for Tolerance Proposal
Cucumber	06987	Volume 2
Squash	08939	Volume 3
Cantaloupe	08940	Volume 4

Review; 3 final reports

FEE CATEGORY: R-170

REGISTRATION FEE: 3 X \$59,976= \$179,928 (See IR-4 Exemption Request below)

ELECTRONIC SUBMISSION TO FOLLOW

The undersigned, Raymond C. Leonard, Associate Coordinator, Interregional Research Project No. 4, State Agricultural Experiment Station, Rutgers, The State University of New Jersey, Princeton, New Jersey 08540, on behalf of the IR-4 Project and the Agricultural Experiment Stations of Oklahoma, California, Arizona, Tennessee, North Carolina, Georgia and Florida (cucumber); Oklahoma, Puerto Rico, California, North Carolina, Georgia, Florida, Tennessee and Indiana (squash); and Oklahoma, Puerto Rico, California, Arizona, North Carolina, Georgia, Florida, Tennessee and Indiana (cantaloupe) submit the present petition pursuant to

Section 408(e) of the Federal Food, Drug and Cosmetic Act, as amended, with respect to the pesticide chemical, emamectin (40 CFR 180.505).

We request that this petition be reviewed under the Pesticide Registration Improvement Act and that EPA should exempt the registration fee for review of these uses.

List of Studies Submitted in Support of Proposed Tolerance for emamectin:

Volume No.	Volume Title
1	Administrative Volume (Petition Proposing a Crop Group Tolerance for EMAMECTIN BENZOATE in or on Crops in VEGETABLE, CUCURBIT, GROUP 9
2	Emamectin Benzoate: Magnitude of the Residue on Cucumber
3	Emamectin Benzoate: Magnitude of the Residue on Squash
4	Emamectin Benzoate: Magnitude of the Residue on Cantaloupe

For neurotoxicity and immunotoxicity studies:

According to the enclosed letter from Syngenta Crop Protection, LLC dated May 26, 2011, the required study for subchronic neurotoxicity (OPPTS Guideline 870.6200) was submitted to EPA on December 18, 1992 (MRID No. 42743628) and the required study for acute neurotoxicity (OPPTS Guideline 870.6200) was submitted on December 21, 1992 (MRID No. 42743618). The immunotoxicity study (OPPTS Guideline 870.7800) is planned to be initiated in September 2011 with an April 2012 EPA submission date. The results of the study are not expected to impact the human health risk assessment.

IR-4 is also submitting the following that has been provided by Syngenta Crop Protection:

NOTICE OF FILING for the use of emamectin in or on the raw agricultural commodities within VEGETABLE, CUCURBIT, GROUP 9

Emamectin benzoate technical II:

- EPA Form 8570-1 Registration Package Form for emamectin benzoate technical II
- EPA Form 8570-34 Certification with Respect to Citation of Data for emamectin benzoate technical II
- EPA Form 8570-35 emamectin benzoate technical II Data Matrix both private and public versions
- emamectin benzoate technical II (5 copies+ one with highlighted changes)

PROCLAIM

- EPA Form 8570-1 Registration Package Form for PROCLAIM
- EPA Form 8570-27 Formulators Exemption Statement Formulators Exemption Statement.
- EPA Form 8570-34 Certification with Respect to Citation of Data for PROCLAIM
- EPA Form 8570-35 PROCLAIM Data Matrix both private and public versions
- PROCLAIM label (5 copies+ one with highlighted changes)

Please contact John Abbott, Syngenta, Tel. No. (800) 334- 9481 or by e-mail at john.abbott@syngenta.com if necessary.

Per



John D. Abbott, Ph.D., CPH
Regulatory Team Leader
(336) 632-7074 (phone)
(336) 632-5688 (fax)
(336) 253-9666 (mobile)
john.abbott@syngenta.com

Syngenta Crop Protection, LLC
P.O. Box 18300
Greensboro, NC 27419-8300
www.syngenta.com

April 15, 2011

Barbara Madden
Document Processing Desk (IR-4)
USEPA Office of Pesticide Programs (7504P)
One Potomac Yard
2777 S. Crystal Drive, Room S-4900
Arlington, VA 22202

ATTENTION: Ms. Barbara Madden

SUBJECT: EMAMECTIN BENZOATE PETITION FOR TOLERANCE
Proclaim 5SG
EPA Reg. No. 100-904
Establishing a Tolerance for Cucurbit Vegetables, Crop Group 9
AUTHORIZATION TO CITE SYNGENTA'S EMAMECTIN BENZOATE DATA

Dear Ms. Madden:

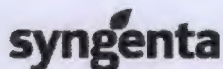
Syngenta Crop Protection, LLC herewith authorizes the Registration Division of the Office of Pesticide Programs of the Environmental Protection Agency to refer to all data for the subject product submitted by Syngenta which are considered necessary to support the IR-4 petition for establishing residue tolerances of emamectin benzoate on cucurbit vegetables (Crop Group 9).

This authorization is qualified to the extent, however, that: 1) the applicant or any other person except your agency shall not have access to said data unless specifically authorized in writing by Syngenta, or when in the opinion of your agency it is required in judicial or administrative proceedings; 2) this authorization shall not be construed as authorization to use or consider said data, directly or indirectly, in support of any subsequent application submitted by the applicant; and 3) this authorization shall not be transferred by the applicant in any manner whatsoever without express prior consent of Syngenta.

Please contact me at 336.632.7074 (office) or 336.253.9666 (mobile) if there are any questions.

Sincerely,

John D. Abbott, Ph.D., CPH
Team Leader
Fungicides and Insecticides
NAFTA Regulatory Affairs



Regulatory Affairs
P.O. Box 18300
Greensboro, NC 27419-8300

Telephone: (336) 632-7074
Fax: (336) 632-5688

May 26, 2011
Document Processing Desk (IR-4)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive – Room S-4900
Arlington, VA 22202

Attention: Ms. Barbara Madden:

SUBJECT: Enamectin benzoate Petition for a Tolerance as End-Use Product Proclaim Insecticide (EPA Reg. No. 100-904) and as Enamectin benzoate Technical II (100-1270) Status on Immunotoxicity and Neurotoxicity Studies

Dear Ms. Madden:

Syngenta Crop Protection, LLC would like to provide an update on the status of the required guideline studies (immunotoxicity and neurotoxicity) for emamectin benzoate. The acute neurotoxicity study was completed and submitted on December 21, 1992 (MRID No. 42743618). The subchronic neurotoxicity study was completed and submitted on December 18, 1992 (MRID No. 42743628). The immunotoxicity study is planned to be initiated September 2011 and submitted April 2012.

As stated in the EPA Human Health Risk Assessment dated July 31, 2008 (Decision No. 384481), Section 3.2.1, FQPA Considerations, Adequacy of the Toxicity Database, "the toxicology data base for emamectin is complete and sufficient to determine human hazard and FQPA assessments," and "at this time, the acute and chronic RfD's are 0.00025 mg/kg/day and 0.000075 mg/kg/day, respectively; and a database uncertainty factor is not necessary to account for a lack of an immunotoxicity study."

If you have any questions or comments, please contact me at 336-632-7074 or by email at john.abbott@syngenta.com. Thank you for your assistance.

Sincerely,

John D. Abbott, Ph.D., CPH
Team Leader
NAFTA Regulatory Affairs-Herbicides



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M STREET, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Syngenta Crop Protection, LLC Box 18300 Greensboro NC 27419	EPA Registration Number/File Symbol 100-1270
Active Ingredient(s) and/or representative test compound(s) Eamectin Benzoate	Date 4-14-2011
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food	Product Name Eamectin Benzoate Technical II

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application to the extent required by FIFRA.

SECTION III: CERTIFICATION

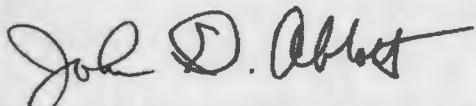
I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 4-14-2011	Typed or Printed Name and Title John D. Abbott, Ph.D., CPH, Team Lead, Fungicides & Insecticides
--	-------------------	---

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 4/15/2011

Reg. No: 100-1270

Page 1 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
Cite-All	Cite-All	Cite-All (AHE	AGRICULTURAL HAN	PER	
Cite-All	Cite-All	Cite-All (ART	AGRICULTURAL REE	PER	
Cite-All	Cite-All	Cite-All (FES	FIFRA ENDANGERED	PER	
Cite-All	Cite-All	Cite-All (ORE	OUTDOOR RESIDENT	PER	
Cite-All	Cite-All	Cite-All (REJ	RESIDENTIAL EXPOS	PER	
Cite-All	Cite-All	Cite-All (SDT	SPRAY DRIFT TF	PER	
830.1550	Product identity and composition	47002101	SYNGENTA	OWN	
830.1550	Product identity and composition	47002102	SYNGENTA	OWN	
830.1600	Description of materials used to produce the product	47002102	SYNGENTA	OWN	
830.1620	Description of production process	47002102	SYNGENTA	OWN	
830.1670	Discussion of formation of impurities	47002102	SYNGENTA	OWN	
830.1700	Preliminary analysis	47002101	SYNGENTA	OWN	

John D. Abbott Ph.D., CPH, NAFTA Insecticide Team Leader

Date: 4/15/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 4/15/2011

Reg. No: 100-1270

Page 2 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
830.1700	Preliminary analysis	47002102	SYNGENTA	OWN	
830.1750	Certified limits	47002102	SYNGENTA	OWN	
830.1800	Enforcement analytical method	47002102	SYNGENTA	OWN	
830.6302	Color	47002103	SYNGENTA	OWN	
830.6303	Physical state	47002103	SYNGENTA	OWN	
830.6304	Odor	47002103	SYNGENTA	OWN	
830.6313	Stability to normal and elevated temperatures, metals,	47002103	SYNGENTA	OWN	
830.6314	Oxidation/reduction: chemical incompatibility	47002103	SYNGENTA	OWN	
830.6315	Flammability	47002103	SYNGENTA	OWN	
830.6316	Explosibility	47002103	SYNGENTA	OWN	
830.6317	Storage Stability	47002103	SYNGENTA	OWN	
830.6319	Miscibility	47002103	SYNGENTA	OWN	

John D. Abbott Ph.D., CPH, NAFTA Insecticide Team Leader

Date: 4/15/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 4/15/2011		Reg. No: 100-1270		Page 3 of 24	
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419		Product: EMAMECTIN BENZOATE TECHNICAL II			
Ingredient: Emamectin					
Guideline Reference Number	Name	MRID	Submitter	Status	Notes
830.6320	Corrosion characteristics	47002103	SYNGENTA	OWN	
830.6321	Dielectric breakdown voltage	47002103	SYNGENTA	OWN	
830.7000	pH	47002103	SYNGENTA	OWN	
830.7050	UV/Visible absorption	47002103	SYNGENTA	OWN	
830.7100	Viscosity	47002103	SYNGENTA	OWN	
830.7200	Melting point/melting range	47002103	SYNGENTA	OWN	
830.7220	Boiling point/boiling range	47002103	SYNGENTA	OWN	
830.7300	Density/relative density/bulk density	47002103	SYNGENTA	OWN	
830.7370	Dissociation constants in water	47002103	SYNGENTA	OWN	
830.7550	Partition coefficient (n-octanol/water), shake flask met	47002103	SYNGENTA	OWN	
830.7840	Water solubility: column elution method, shake flask	47002103	SYNGENTA	OWN	
830.7950	Water solubility, Vapor pressure	47002103	SYNGENTA	OWN	

John D. Abbott Ph.D., CPH, NAFTA Insecticide Team Leader

Date: 4/15/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 4/15/2011		Reg. No: 100-1270		Page 4 of 24	
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419		Product: EMAMECTIN BENZOATE TECHNICAL II			
Ingredient: Emamectin					
Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850 Series	Ecological Effects	47767401	SYNGENTA	OWN	
870.1100	Acute oral toxicity	47002104	SYNGENTA	OWN	
870.1100	Acute oral toxicity	47002105	SYNGENTA	OWN	
870.1100	Acute oral toxicity	47153906	SYNGENTA	OWN	
870.1100	Acute oral toxicity	47153907	SYNGENTA	OWN	
870.1100	Acute oral toxicity	47309303	SYNGENTA	OWN	
870.1200	Acute dermal toxicity	47002106	SYNGENTA	OWN	
870.1200	Acute dermal toxicity	47153907	SYNGENTA	OWN	
870.1200	Acute dermal toxicity	47153908	SYNGENTA	OWN	
870.1200	Acute dermal toxicity	47309304	SYNGENTA	OWN	
870.1300	Acute inhalation toxicity	47002107	SYNGENTA	OWN	
870.1300	Acute inhalation toxicity	47153907	SYNGENTA	OWN	

John D. Abbott Ph.D., CPH, NAFTA Insecticide Team Leader

Date: 4/15/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 4/15/2011

Reg. No: 100-1270

Page 5 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Eamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.1300	Acute inhalation toxicity	47309305	SYNGENTA	OWN	
870.2400	Acute eye irritation	47002108	SYNGENTA	OWN	
870.2400	Acute eye irritation	47153907	SYNGENTA	OWN	
870.2400	Acute eye irritation	47153909	SYNGENTA	OWN	
870.2400	Acute eye irritation	47309306	SYNGENTA	OWN	
870.2500	Acute dermal irritation	47002109	SYNGENTA	OWN	
870.2500	Acute dermal irritation	47153907	SYNGENTA	OWN	
870.2500	Acute dermal irritation	47153910	SYNGENTA	OWN	
870.2500	Acute dermal irritation	47309307	SYNGENTA	OWN	
870.2600	Skin sensitization	47002110	SYNGENTA	OWN	
870.2600	Skin sensitization	47153907	SYNGENTA	OWN	
870.2600	Skin sensitization	47153911	SYNGENTA	OWN	

870.2600

John D. Abbott Ph.D., CPH, NAFTA Insecticide Team Leader

870.2600

Date: 4/15/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 4/15/2011

Reg. No: 100-1270

Page 6 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Eameectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.2600	Skin sensitization	47309308	SYNGENTA	OWN	
870.3100	90-Day oral toxicity	42743620	MERCK & CO., INC.	OWN	
870.3100	90-Day oral toxicity	42743621	MERCK & CO., INC.	OWN	
870.3100	90-Day oral toxicity	42743622	MERCK & CO., INC.	OWN	
870.3100	90-Day oral toxicity	42743623	MERCK & CO., INC.	OWN	
870.3100	90-Day oral toxicity	42794201	MERCK & CO., INC.	OWN	
870.3100	90-Day oral toxicity	43868103	MERCK & CO., INC.	OWN	
870.3150	Subchronic nonrodent oral toxicity - 90-day	42743620	MERCK & CO., INC.	OWN	
870.3150	Subchronic nonrodent oral toxicity - 90-day	42743621	MERCK & CO., INC.	OWN	
870.3150	Subchronic nonrodent oral toxicity - 90-day	42743622	MERCK & CO., INC.	OWN	
870.3150	Subchronic nonrodent oral toxicity - 90-day	42743623	MERCK & CO., INC.	OWN	
870.3150	Subchronic nonrodent oral toxicity - 90-day	42794201	MERCK & CO., INC.	OWN	

John D. Abbott Ph.D., CPH, NAFTA Insecticide Team Leader

Date: 4/15/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 4/15/2011

Reg. No: 100-1270

Page 7 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Eameectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.3150	Subchronic nonrodent oral toxicity - 90-day	43868103	MERCK & CO., INC.	OWN	
870.3200	Repeated dose dermal toxicity - 21/28 day	42743625	MERCK & CO., INC.	OWN	
870.3200	Repeated dose dermal toxicity - 21/28 day	44007902	MERCK & CO., INC.	OWN	
870.3700	Prenatal developmental toxicity study	42743631	MERCK & CO., INC.	OWN	
870.3700	Prenatal developmental toxicity study	42743632	MERCK & CO., INC.	OWN	
870.3700	Prenatal developmental toxicity study	42743634	MERCK & CO., INC.	OWN	
870.3700	Prenatal developmental toxicity study	42743635	MERCK & CO., INC.	OWN	
870.3700	Prenatal developmental toxicity study	42743636	MERCK & CO., INC.	OWN	
870.3800	Reproduction and fertility effects	42743633	MERCK & CO., INC.	OWN	
870.3800	Reproduction and fertility effects	42851511	MERCK & CO., INC.	OWN	
870.4100	Chronic toxicity	42743624	MERCK & CO., INC.	OWN	
870.4100	Chronic toxicity	42851510	MERCK & CO., INC.	OWN	

John D. Abbott Ph.D., CPH, NAFTA Insecticide Team Leader

Date: 4/15/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 4/15/2011

Reg. No: 100-1270

Page 8 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.4100	Chronic toxicity	42868902	MERCK & CO., INC.	OWN	
870.4100	Chronic toxicity	43868104	MERCK & CO., INC.	OWN	
870.4200	Carcinogenicity	43868104	MERCK & CO., INC.	OWN	
870.4200	Carcinogenicity	43868105	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42743637	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42743638	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42743639	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42851512	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42851513	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42851514	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42851515	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42851516	MERCK & CO., INC.	OWN	

John D. Abbott Ph.D., CPH, NAFTA Insecticide Team Leader

Date: 4/15/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 4/15/2011		Reg. No: 100-1270		Page 9 of 24	
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419		Product: EMAMECTIN BENZOATE TECHNICAL II			
Ingredient: Eamectin					
Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.5000	Genetic Toxicity tests	42851517	MERCK & CO., INC.	OWN	
870.5100	Bacterial reverse mutation test	47002111	SYNGENTA	OWN	
870.6100	Acute and 28-day delayed neurotoxicity of organopho	42743611	MERCK & CO., INC.	OWN	
870.6100	Acute and 28-day delayed neurotoxicity of organopho	42743614	MERCK & CO., INC.	OWN	
870.6100	Acute and 28-day delayed neurotoxicity of organopho	42743626	MERCK & CO., INC.	OWN	
870.6100	Acute and 28-day delayed neurotoxicity of organopho	42743627	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42743618	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42743619	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42743624	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42743628	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42743629	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42743630	MERCK & CO., INC.	OWN	

John D. Abbott Ph.D., CPH, NAFTA Insecticide Team Leader

Date: 4/15/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 4/15/2011

Reg. No: 100-1270

Page 10 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Eamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.6200	Neurotoxicity screening battery	42851503	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851504	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851505	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851506	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851507	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851508	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851509	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851510	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42868902	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	43868104	MERCK & CO., INC.	OWN	
870.7485	Metabolism and pharmacokinetics	42743640	MERCK & CO., INC.	OWN	
870.7485	Metabolism and pharmacokinetics	42743641	MERCK & CO., INC.	OWN	

John D. Abbott Ph.D., CPH, NAFTA Insecticide Team Leader

Date: 4/15/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 4/15/2011

Reg. No: 100-1270

Page 11 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Eameectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.7485	Metabolism and pharmacokinetics	44030601	MERCK & CO., INC.	OWN	
870.7600	Dermal penetration	43850113	MERCK & CO., INC.	OWN	
810.1000	Product Performance. Overview, Definitions and Gen	47153901	SYNGENTA	OWN	
810.1000	Product Performance. Overview, Definitions and Gen	47153902	SYNGENTA	OWN	
810.1000	Product Performance. Overview, Definitions and Gen	47465501	SYNGENTA	OWN	
810.1000	Product Performance. Overview, Definitions and Gen	47691001	SYNGENTA	OWN	
810.1000	Product Performance. Overview, Definitions and Gen	47878901	SYNGENTA	OWN	
810.3000	General Considerations for Efficacy of Invertebrate C	47153901	SYNGENTA	OWN	
810.3000	General Considerations for Efficacy of Invertebrate C	47153902	SYNGENTA	OWN	
810.3500	Premise Treatments	47153901	SYNGENTA	OWN	
810.3500	Premise Treatments	47153902	SYNGENTA	OWN	
810.3500	Premise Treatments	47153903	SYNGENTA	OWN	

John D. Abbott Ph.D., CPH, NAFTA Insecticide Team Leader

Date: 4/15/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 4/15/2011

Reg. No: 100-1270

Page 12 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Eameectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.4400	Aquatic plant toxicity test using Lemna spp. Tiers I and II	43850108	MERCK & CO., INC.	OWN	
850.4400	Aquatic plant toxicity test using Lemna spp. Tiers I and II	43850109	MERCK & CO., INC.	OWN	
850.5400	Algal toxicity, Tiers 1 and 2	43850108	MERCK & CO., INC.	OWN	
850.5400	Algal toxicity, Tiers 1 and 2	43850109	MERCK & CO., INC.	OWN	
875.2100	Foliar dislodgeable residue dissipation	43850126	MERCK & CO., INC.	OWN	
875.2100	Foliar dislodgeable residue dissipation	44007903	MERCK & CO., INC.	OWN	
875.2200	Soil residue dissipation	43850126	MERCK & CO., INC.	OWN	
875.2200	Soil residue dissipation	44007903	MERCK & CO., INC.	OWN	
875.2400	Dermal exposure	43850126	MERCK & CO., INC.	OWN	
875.2400	Dermal exposure	43943301	MERCK & CO., INC.	OWN	
875.2600	Biological Monitoring	43943301	MERCK & CO., INC.	OWN	
850.3020	Honey bee acute contact toxicity	42851530	MERCK & CO., INC.	OWN	

John D. Abbott Ph.D., CPH, NAFTA Insecticide Team Leader

Date: 4/15/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 4/15/2011		Reg. No: 100-1270		Page 13 of 24	
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419		Product: EMAMECTIN BENZOATE TECHNICAL II			
Ingredient: Emamectin					
Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.3030	Honey bee toxicity of residues on foliage	43393006	MERCK & CO., INC.	OWN	
161-1	Hydrolysis - laboratory	42743642	MERCK & CO., INC.	OWN	
161-2	Photodegradation in water - laboratory	43404301	MERCK & CO., INC.	OWN	
161-2	Photodegradation in water - laboratory	43850114	MERCK & CO., INC.	OWN	
161-3	Photodegradation in soil - laboratory	43404302	MERCK & CO., INC.	OWN	
161-3	Photodegradation in soil - laboratory	44010001	MERCK & CO., INC.	OWN	
161-4	Photodegradation in Air	44007906	MERCK & CO., INC.	OWN	
161-4	Photodegradation in Air	44007907	MERCK & CO., INC.	OWN	
162-1	Aeroic Soil metabolism	43235101	MERCK & CO., INC.	OWN	
162-1	Aeroic Soil metabolism	43404303	MERCK & CO., INC.	OWN	
162-1	Aeroic Soil metabolism	43850115	MERCK & CO., INC.	OWN	
162-1	Aeroic Soil metabolism	44007905	MERCK & CO., INC.	OWN	

John D. Abbott Ph.D., CPH, NAFTA Insecticide Team Leader

Date: 4/15/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 4/15/2011		Reg. No: 100-1270		Page 14 of 24	
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419		Product: EMAMECTIN BENZOATE TECHNICAL II			
Ingredient: Eameectin					
Guideline Reference Number	Name	MRID	Submitter	Status	Notes
162-1	Aeroic Soil metabolism	44010001	MERCK & CO., INC.	OWN	
162-2	Anaerobic Soil Metabolism	43850116	MERCK & CO., INC.	OWN	
163-1	Leaching and adsorption/desorption -- laboratory	42743643	MERCK & CO., INC.	OWN	
163-1	Leaching and adsorption/desorption -- laboratory	43850117	MERCK & CO., INC.	OWN	
164-1	Soil dissipation -- field	43404304	MERCK & CO., INC.	OWN	
164-1	Soil dissipation -- field	43850118	MERCK & CO., INC.	OWN	
171-11	Crop field trials	44715103	SYNGENTA	OWN	
860.1000	Background	44715103	SYNGENTA	OWN	
860.1000	Background	46587001	SYNGENTA	OWN	
860.1000	Background	46587002	SYNGENTA	OWN	
860.1000	Background	47723501	SYNGENTA	OWN	
860.1300	Nature of the residue -- plants, livestock	42851522	MERCK & CO., INC.	OWN	

John D. Abbott Ph.D., CPH, NAFTA Insecticide Team Leader

Date: 4/15/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 4/15/2011

Reg. No: 100-1270

Page 15 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
860.1300	Nature of the residue -- plants, livestock	42868904	MERCK & CO., INC.	OWN	
860.1300	Nature of the residue -- plants, livestock	43404307	MERCK & CO., INC.	OWN	
860.1300	Nature of the residue -- plants, livestock	43850121	MERCK & CO., INC.	OWN	
860.1300	Nature of the residue -- plants, livestock	43850122	MERCK & CO., INC.	OWN	
860.1300	Nature of the residue -- plants, livestock	43850123	MERCK & CO., INC.	OWN	
860.1300	Nature of the residue -- plants, livestock	43850124	MERCK & CO., INC.	OWN	
860.1300	Nature of the residue -- plants, livestock	43850125	MERCK & CO., INC.	OWN	
860.1300	Nature of the residue -- plants, livestock	44007904	MERCK & CO., INC.	OWN	
860.1300	Nature of the residue -- plants, livestock	44007906	MERCK & CO., INC.	OWN	
860.1300	Nature of the residue -- plants, livestock	44007907	MERCK & CO., INC.	OWN	
860.1300	Nature of the residue -- plants, livestock	44300102	MERCK & CO., INC.	OWN	
860.1300	Nature of the residue -- plants, livestock	44300107	MERCK & CO., INC.	OWN	

John D. Abbott Ph.D., CPH, NAFTA Insecticide Team Leader

Date: 4/15/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 4/15/2011		Reg. No: 100-1270		Page 16 of 24	
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419		Product: EMAMECTIN BENZOATE TECHNICAL II			
Ingredient: Eamectin					
Guideline Reference Number	Name	MRID	Submitter	Status	Notes
860.1300	Nature of the residue – plants, livestock	44313201	MERCK & CO., INC.	OWN	
860.1300	Nature of the residue – plants, livestock	44596301	SYNGENTA	OWN	
860.1300	Nature of the residue – plants, livestock	44883710	SYNGENTA	OWN	
860.1300	Nature of the residue – plants, livestock	44883711	SYNGENTA	OWN	
860.1300	Nature of the residue – plants, livestock	44883712	SYNGENTA	OWN	
860.1300	Nature of the residue – plants, livestock	44883713	SYNGENTA	OWN	
860.1300	Nature of the residue – plants, livestock	44883714	SYNGENTA	OWN	
860.1300	Nature of the residue – plants, livestock	45209801	SYNGENTA	OWN	
860.1340	Residue analytical method	42851520	MERCK & CO., INC.	OWN	
860.1340	Residue analytical method	42851521	MERCK & CO., INC.	OWN	
860.1340	Residue analytical method	42868903	MERCK & CO., INC.	OWN	
860.1340	Residue analytical method	43393011	MERCK & CO., INC.	OWN	

EPA

H4

John D. Abbott Ph.D., CPH, NAFTA Insecticide Team Leader

Date: 4/15/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 4/15/2011

Reg. No: 100-1270

Page 17 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Eamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
860.1340	Residue analytical method	43393012	MERCK & CO., INC.	OWN	
860.1340	Residue analytical method	43415301	MERCK & CO., INC.	OWN	
860.1340	Residue analytical method	43850121	MERCK & CO., INC.	OWN	
860.1340	Residue analytical method	43850122	MERCK & CO., INC.	OWN	
860.1340	Residue analytical method	44030602	MERCK & CO., INC.	OWN	
860.1340	Residue analytical method	44300101	MERCK & CO., INC.	OWN	
860.1340	Residue analytical method	44300103	MERCK & CO., INC.	OWN	
860.1340	Residue analytical method	44300106	MERCK & CO., INC.	OWN	
860.1340	Residue analytical method	44596301	SYNGENTA	OWN	
860.1340	Residue analytical method	44795001	SYNGENTA	OWN	
860.1340	Residue analytical method	44883707	SYNGENTA	OWN	
860.1340	Residue analytical method	44883708	SYNGENTA	OWN	

John D. Abbott Ph.D., CPH, NAFTA Insecticide Team Leader

Date: 4/15/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 4/15/2011		Reg. No: 100-1270		Page 18 of 24	
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419		Product: EMAMECTIN BENZOATE TECHNICAL II			
Ingredient: Eamectin					
Guideline Reference Number	Name	MRID	Submitter	Status	Notes
860.1340	Residue analytical method	44883709	SYNGENTA	OWN	
860.1340	Residue analytical method	44883715	SYNGENTA	OWN	
860.1340	Residue analytical method	44883716	SYNGENTA	OWN	
860.1340	Residue analytical method	45209801	SYNGENTA	OWN	
860.1340	Residue analytical method	45209802	SYNGENTA	OWN	
860.1340	Residue analytical method	45209803	SYNGENTA	OWN	
860.1340	Residue analytical method	45899801	SYNGENTA	OWN	
860.1340	Residue analytical method	48170001	SYNGENTA	OWN	
860.1340	Residue analytical method	48170002	SYNGENTA	OWN	
860.1380	Storage stability data	46734701	SYNGENTA	OWN	
860.1380	Storage stability data	47296001	SYNGENTA	OWN	
860.1380	Storage stability data	48193601	SYNGENTA	OWN	

John D. Abbott Ph.D., CPH, NAFTA Insecticide Team Leader

Date: 4/15/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 4/15/2011

Reg. No: 100-1270

Page 19 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
860.1500	Crop field trials	44715103	SYNGENTA	OWN	
860.1500	Crop field trials	45209802	SYNGENTA	OWN	
860.1500	Crop field trials	45209803	SYNGENTA	OWN	
860.1500	Crop field trials	46587001	SYNGENTA	OWN	
860.1500	Crop field trials	46587002	SYNGENTA	OWN	
860.1500	Crop field trials	46783701	SYNGENTA	OWN	
860.1500	Crop field trials	47002101	SYNGENTA	OWN	
860.1500	Crop field trials	47243301	SYNGENTA	OWN	
860.1500	Crop field trials	47723501	SYNGENTA	OWN	
860.1520	Processed food/feed	46587002	SYNGENTA	OWN	
860.1520	Processed food/feed	46783701	SYNGENTA	OWN	
860.1850	Confined accumulation in rotational crops	43850119	MERCK & CO., INC.	OWN	

John D. Abbott Ph.D., CPH, NAFTA Insecticide Team Leader

Date: 4/15/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 4/15/2011

Reg. No: 100-1270

Page 20 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.1010	Aquatic invertigrade acute toxicity test, freshwater dap	42743603	MERCK & CO., INC.	OWN	
850.1010	Aquatic invertigrade acute toxicity test, freshwater dap	44007901	MERCK & CO., INC.	OWN	
850.1025	Oyster acute toxicity test (shell deposition)	43393001	MERCK & CO., INC.	OWN	
850.1025	Oyster acute toxicity test (shell deposition)	43393002	MERCK & CO., INC.	OWN	
850.1025	Oyster acute toxicity test (shell deposition)	43393003	MERCK & CO., INC.	OWN	
850.1025	Oyster acute toxicity test (shell deposition)	44007912	MERCK & CO., INC.	OWN	
850.1025	Oyster acute toxicity test (shell deposition)	44007913	MERCK & CO., INC.	OWN	
850.1025	Oyster acute toxicity test (shell deposition)	44007914	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	43393001	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	43393002	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	43393003	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	44007912	MERCK & CO., INC.	OWN	

77910

John D. Abbott Ph.D., CPH, NAFTA Insecticide Team Leader

843

Date: 4/15/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 4/15/2011		Reg. No: 100-1270		Page 21 of 24	
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419		Product: EMAMECTIN BENZOATE TECHNICAL II			
Ingredient: Emamectin					
Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.1035	Mysid acute toxicity test	44007913	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	44007914	MERCK & CO., INC.	OWN	
850.1045	Penaeid acute toxicity test	43393001	MERCK & CO., INC.	OWN	
850.1045	Penaeid acute toxicity test	43393002	MERCK & CO., INC.	OWN	
850.1045	Penaeid acute toxicity test	43393003	MERCK & CO., INC.	OWN	
850.1045	Penaeid acute toxicity test	44007912	MERCK & CO., INC.	OWN	
850.1045	Penaeid acute toxicity test	44007913	MERCK & CO., INC.	OWN	
850.1045	Penaeid acute toxicity test	44007914	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	43393001	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	43393002	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	43393003	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	44007912	MERCK & CO., INC.	OWN	

John D. Abbott Ph.D., CPH, NAFTA Insecticide Team Leader

Date: 4/15/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 4/15/2011

Reg. No: 100-1270

Page 22 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.1055	Bivalve acute toxicity test (embryo larval)	44007913	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	44007914	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	42743602	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	42851529	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	43393001	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	43393002	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	43393003	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	43850106	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	44007912	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	44007913	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	44007914	MERCK & CO., INC.	OWN	
850.1300	Daphnid chronic toxicity test	43393004	MERCK & CO., INC.	OWN	

John D. Abbott Ph.D., CPH, NAFTA Insecticide Team Leader

Date: 4/15/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 4/15/2011

Reg. No: 100-1270

Page 23 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.1300	Daphnid chronic toxicity test	43850107	MERCK & CO., INC.	OWN	
850.1300	Daphnid chronic toxicity test	44305601	MERCK & CO., INC.	OWN	
850.1300	Daphnid chronic toxicity test	45833001	SYNGENTA	OWN	
850.1350	Mysid chronic toxicity test	43393004	MERCK & CO., INC.	OWN	
850.1350	Mysid chronic toxicity test	43850107	MERCK & CO., INC.	OWN	
850.1350	Mysid chronic toxicity test	44305601	MERCK & CO., INC.	OWN	
850.1350	Mysid chronic toxicity test	45833001	SYNGENTA	OWN	
850.1400	Fish early-life stage toxicity test	43393004	MERCK & CO., INC.	OWN	
850.1400	Fish early-life stage toxicity test	43850107	MERCK & CO., INC.	OWN	
850.1400	Fish early-life stage toxicity test	44305601	MERCK & CO., INC.	OWN	
850.1400	Fish early-life stage toxicity test	45833001	SYNGENTA	OWN	
850.1710	Oyster BCF	43393005	MERCK & CO., INC.	OWN	

John D. Abbott Ph.D., CPH, NAFTA Insecticide Team Leader

Date: 4/15/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 4/15/2011		Reg. No: 100-1270		Page 24 of 24	
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419		Product: EMAMECTIN BENZOATE TECHNICAL II			
Ingredient: Enamectin					
Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.1730	Accumulation in fish -- waiver	43393005	MERCK & CO., INC.	OWN	
850.1850	Aquatic organism accumulation	43393005	MERCK & CO., INC.	OWN	
850.2100	Avian acute oral toxicity test	42743601	MERCK & CO., INC.	OWN	
850.2100	Avian acute oral toxicity test	42868905	MERCK & CO., INC.	OWN	
850.2200	Avian dietary toxicity test	42851527	MERCK & CO., INC.	OWN	
850.2200	Avian dietary toxicity test	42851528	MERCK & CO., INC.	OWN	
850.2300	Avian reproduction test	43850104	MERCK & CO., INC.	OWN	
850.2300	Avian reproduction test	43850105	MERCK & CO., INC.	OWN	
850.2300	Avian reproduction test	44007910	MERCK & CO., INC.	OWN	
850.2300	Avian reproduction test	44007911	MERCK & CO., INC.	OWN	

John D. Abbott Ph.D., CPH, NAFTA Insecticide Team Leader

Date: 4/15/2011

Eamectin Benzoate Technical II

An insecticide for formulation into end-use insecticide products intended for non-domestic terrestrial outdoor food use.

Active Ingredient:	
Eamectin Benzoate (CAS No. 155569-91-8)	97.0%
Other Ingredients:	3.0%
Total:	100.0%

KEEP OUT OF REACH OF CHILDREN

WARNING/AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use on label.

EPA Reg. No. 100-1270

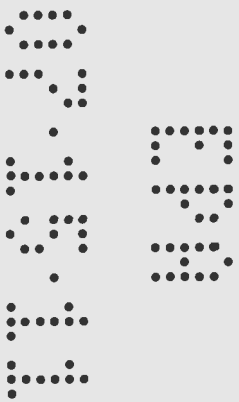
EPA Est. xxxxx

Product of xxxxx

Product ID. xxxx

SCP 1270A-M(draft IR-4 cucurbits)

Net Weight



FIRST AID	
If swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth, if possible. • Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
<p align="center">NOTE TO PHYSICIAN</p> <p>Probably mucosal damage may contraindicate the use of gastric lavage. Early signs of intoxication include dilated pupils, muscular incoordination, and muscle tremors. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements.</p> <p>In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.</p>	
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p>	
<p align="center">HOT LINE NUMBER</p> <p align="center">For 24-Hour Medical Emergency Assistance (Human or Animal) or Chemical Emergency Assistance (Spill, Leak, Fire, or Accident), Call 1-800-888-8372</p>	

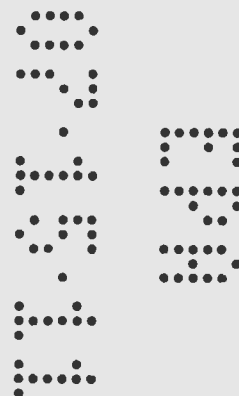
PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals**WARNING/AVISO**

May be fatal if inhaled or swallowed. Causes moderate eye irritation. Harmful if absorbed through skin. Do not breathe dust. Avoid contact with skin, eyes, or clothing. The following protective clothing must be worn during all handling and formulation operations: airline mask or air supplied hood, chemical-resistant goggles and gloves, full body garments with shoe protectors and head cover. Disposable clothing is recommended. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

Environmental Hazards

This pesticide is toxic to fish, birds, mammals, and aquatic invertebrates. Do not discharge effluent containing this active ingredient into lakes, streams, ponds, estuaries, oceans, or other public waters, unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit, and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.



CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, LLC or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and (2) Buyer and User assume the risk of any such use. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.**

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Instructions to Formulators

Formulators using this product are responsible for obtaining Environmental Protection Agency registration for their formulated products.

This technical product may be used only for formulation of end-use insecticides for the uses listed below:

Agricultural crops (Terrestrial Food Crops):

- *Brassica* leafy vegetables crop group 5
- Cotton
- Cucurbit vegetables crop group 9
- Fruiting vegetables (except cucurbits) crop group 8
- Leafy vegetables (except *Brassica*) crop group 4
- Pome fruit crop group 11
- Tree nuts crop group 14 plus pistachios
- Tobacco
- Turnip greens (tops, leaves)*

*For use on turnip varieties grown for leaves only. Do not use on turnip varieties grown for roots or dual-purpose varieties grown for roots and leaves.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage

Store in a tightly closed original container in a cool, dry place. Do not store near food or feed.

Pesticide Disposal

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Handling

Bags: Non-refillable container. Do not reuse or refill this container. Completely empty bag into formulation equipment. Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

Fiber Drums with Liners: Non-refillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. Then offer for recycling if available or dispose of liner in a sanitary landfill or by incineration. If drum is contaminated and cannot be reused, dispose of it in a manner required by its liner.

CONTAINER IS NOT SAFE FOR FOOD, FEED, OR DRINKING WATER.

Note: For minor spills, leaks, etc. follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during clean up and disposal of wastes.

The Syngenta logo and the CP FRAME  are trademarks of a Syngenta Group Company.

©2011 Syngenta

For non-emergency (e.g. current product information)
call Syngenta Crop Protection, LLC at 1-800-334-9481

Manufactured for:
Syngenta Crop Protection, LLC
P.O. Box 18300
Greensboro, North Carolina 27419-8300

SCP 1270A-M(draft IR-4 cucurbits)

EmaBenzTech II 1270A-M(draft IR-4 cucurbits) APR2011 – pl – 4/15/11
000100-01270.20110415.EMA-BENZ-TECH-II_AMEND_APR2011-HI.pdf

Harris, Thomas

*Copy FYI
tracked under 100-904*

From: Harris, Thomas
Sent: Monday, April 29, 2013 1:40 PM
To: tammy.tyler@syngenta.com
Subject: FW: Analytical reference standards for emamectin benzoate are needed.
Attachments: Ltr to EPA emamectin - analy ref standards 10-12-12.pdf; HED.122806.20121120.waive only ref std for some metabolites.DP405982.MEM.pdf

Tammy,

Cleaning up some paperwork and not sure if I ever sent the final EPA decision memo to Syngenta.

For emamectin, HED had noted that some material for the analytical reference standards needed updating. Carolyn took care of this but submitted a waiver request for submission of analytical reference standards for two metabolites (attached along with email history). The waiver was granted (copy of EPA review is attached). No further action required by Syngenta at this time.

Tom Harris
EPA/OCSPP/OPP/RD
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov

From: Thomas Harris [mailto:harris.thomas@epamail.epa.gov]
Sent: Monday, April 29, 2013 1:35 PM
To: Harris, Thomas
Subject: Fw: Analytical reference standards for emamectin benzoate are needed.

Tom Harris
EPA/OCSPP/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit <http://www.epa.gov/pesticides>

----- Forwarded by Thomas Harris/DC/USEPA/US on 04/29/2013 01:35 PM -----

From: <carolyn.brinkley@syngenta.com>
To: Thomas Harris/DC/USEPA/US@EPA
Date: 10/12/2012 02:51 PM
Subject: RE: Analytical reference standards for emamectin benzoate are needed.

e-file: emamectin tolerance - (IR-4) cucurbits/ EPA requirement re: analytical ref standards at EPA Repository

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

Date: 11/20/12

SUBJECT: Emamectin Benzoate. ~~Analytical Reference~~ Standards.

PC Code: 122806

Decision No.: 470695

Petition Nos.: 1E7904

Risk Assessment Type: NA

TXR No.: NA

MRID Nos.: NA

DP Barcode: D405982

Registration No.: 100-904

Regulatory Action: Section 3 Registration

Case No.: NA

CAS No.: 155569-91-8

40 CFR: 180.505

FROM: Nancy Dodd, Chemist *Nancy Dodd*
Risk Assessment Branch III (RAB3)
Health Effects Division (HED) (7509P)

THROUGH: Leung Cheng, Senior Chemist *Leung Cheng*
RAB3/HED (7509P)

TO: John Hebert/Thomas Harris, RM #07
Registration Division (RD) (7505P)

I. CONCLUSIONS/RECOMMENDATIONS

Analytical reference standards for emamectin 8,9-Z isomer of B_{1a} and MFB_{1a} (NOA415692) have been sent to the EPA repository as requested.

HED waives the requirement for a separate analytical reference standard for 8,9-Z B_{1b} since it is a minor component of the residue as compared to 8,9-Z B_{1a}.

II. ACTION REQUESTED

The petitioner was requested to supply the following analytical reference standards:

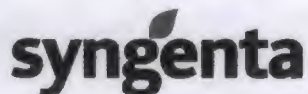
- The standard for emamectin 8,9-Z isomer of B_{1a} (NOA 438376) expired on 3/31/2012. An updated certificate of analysis or a new analytical reference standard must be provided to the EPA National Pesticide Standards Repository.
- Analytical reference standards for MFB_{1a} (NOA415692) and 8,9-Z B_{1b} are currently unavailable at the Repository. Analytical reference standards must be provided.

III. BACKGROUND

Analytical reference standards were requested in connection with PP#1E7904 on cucurbits (D392510, N. Dodd, 8/6/12). At that time, analytical reference standards for emamectin benzoate and its regulated metabolites were available at the EPA National Pesticide Standards Repository (personal communication with T. Cole, ACB, 12/20/11) as follow: emamectin benzoate, mix of B_{1a} and B_{1b} (expiration 2/1/13), emamectin 8,9-Z isomer of B_{1a} (NOA 438376; expiration 3/31/12), emamectin desmethyl (AB_{1a}; NOA 438309; expiration 5/31/13), and emamectin des-*N*-methyl *N*-formyl B_{1a} (FAB_{1a}; NOA 415693; expiration 2/28/13).

IV. RESULTS/DISCUSSION

The petitioner has responded by sending analytical reference standards to the EPA repository for emamectin 8,9-Z isomer of B_{1a} and MFB_{1a} (NOA415692). The petitioner has requested a waiver of the requirement for the 8,9-Z isomer of B_{1b}. The petitioner indicates that 8,9-Z B_{1b} has never been isolated as an analytical reference standard since it is a minor component of the residue.



Carolyn F. Brinkley
Sr. Regulatory Product Manager/NAFTA
Phone: (336) 632-2838
Fax: (336) 632-5688
e-mail: carolyn.brinkley@syngenta.com

Syngenta Crop Protection, LLC
P.O. Box 18300
Greensboro, NC 27419-8300
Phone: (336) 632-6000
www.syngenta.com

October 12, 2012

Mr. Thomas Harris
Insecticide-Rodenticide Branch
U.S. Environmental Protection Agency
Office of Pesticide Programs
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

SUBJECT: EMAMECTIN BENZOATE

**Pending Petition for Tolerance – Cucurbits and Application
to add cucurbits to label for Proclaim® Insecticide (EPA
Reg. No. 100-904)**

**Application for new product registration of ENFOLD™ for
commercial use on ornamentals**

**EPA REQUIREMENT: INSURE EPA REPOSITORY HAS
SPECIFIED ANALYTICAL REFERENCE STANDARDS**

Dear Mr. Harris:

The two registration actions noted in the "Subject" are pending at the EPA, and both actions have a PRIA date of October 25, 2012. With respect to these pending registrations, you informed me via e-mail that Syngenta Crop Protection LLC must insure the EPA Repository has the following:

1. An updated certificate of analysis or a new analytical reference standard for the emamectin 8,9-Z isomer of B1a (NOA 438376)
2. Analytical reference standards for MFB1a (NOA415692) and 8,9-Z B1b.

RESPONSE

With the exception of the analytical reference standard for 8,9-Z B1b, Syngenta provided the requested standards/certificates of analysis to Theresa at the EPA Repository. Her accompanying e-mail of September 27, 2012 confirms that she has the analytical reference standards or updated certificates of analysis, whichever were needed, for the

emamectin 8,9-Z isomer of B1a (NOA 438376) and MFB1a (NOA415692). We were unable to provide the analytical reference standard for 8,9-Z B1b to the EPA Repository and we are requesting a waiver of this requirement. The basis for this waiver request follows.

Waiver Request

In response your recent e-mail noting the requirement to provide the analytical reference standard for 8,9-Z B1b to the EPA Repository, I forwarded the request to my Syngenta colleague who manages analytical standards and who also interacts with Theresa Cole at the EPA Repository. He said no one to his knowledge has ever produced an analytical reference standard for 8,9-Z B1b. Since Merck was the original registrant of emamectin benzoate, he decided to look into the analytical history for emamectin with respect to the tolerances and registrations for this active ingredient. In particular his goal was to determine how Merck addressed 8,9-Z B1b and how EPA responded.

This is what he found:

The original enforcement method submitted by Merck was an HPLC Fluorescence detection method. (available from EPA online). This method does not resolve the 8,9-Z isomers from the parent isomers, so B1a co-elutes with 8,9-Z B1a and it's the same for B1b. For validation, Merck fortified with an 8,9-Z B1a standard + B1a parent and by extension Merck claimed that B1b should behave similarly. So it appears Merck never produced a 8,9-Z B1b standard and because Merck did not resolve the Z isomers in their analysis EPA just set the tolerance limits based on the sums of the Z+parent components. The Novartis/Syngenta analytical method was validated with only the 8,9-Z B1a isomer as well; we've never produced the 8,9-Z B1b analytical reference standard either. In all of the storage stability studies and in everything else we have submitted to the EPA for emamectin benzoate we have only analyzed for the 8,9-Z B1a isomer. And, our current analytical method clearly indicates that we're analyzing only for the 8,9-Z B1a isomer. All of the other metabolites in the tolerance expression are listed as B1a isomers only. So it appears that only the 8,9-Z standard singles out inclusion of B1b in the tolerance expression. This is presumably based on residue studies that accompanied Merck's original tolerance petition; in those studies Merck's analytical method could not distinguish the Z isomers from parent emamectin benzoate.

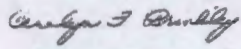
The original metabolism studies showed how little 8,9-Z B1b would be seen in a typical residue profile given the fact that the AI itself only has ~5% of B1b. In addition to Merck's analytical method for emamectin benzoate, Syngenta's EPA-approved method was validated with only the 8,9-Z B1a isomer. It appears that the EPA has historically been satisfied with the method for emamectin that only analyzes for the 8,9-Z B1a isomer which would explain why the Agency has not required an analytical reference standard for the 8,9-Z B1b isomer. Despite this history, if the Agency decided that analyzing for the 8,9-Z B1b isomer was a new requirement, it would likely take Syngenta at least a year before we could provide even a very small quantity of the 8,9-Z B1b isomer. Based on these points and the regulatory history for emamectin benzoate, Syngenta requests the EPA waive the requirement to provide an analytical reference standard for the 8,9-Z B1b

Page 2 of 2

isomer to the EPA Repository.

If you have any questions about our response and our waiver request, please call me at (336) 632 -2838.

Sincerely yours,



Carolyn F. Brinkley
Sr. Regulatory Product Manager/ NAFTA Insecticides
Regulatory Affairs



RE: Analytical reference standards for emamectin benzoate are needed.

carolyn.brinkley

to:

Thomas Harris

10/12/2012 02:51 PM

Hide Details

From: <carolyn.brinkley@syngenta.com>

To: Thomas Harris/DC/USEPA/US@EPA

2 Attachments



image001.gif Ltr to EPA emamectin - analy ref standards 10-12-12.pdf

e-file: emamectin tolerance - (IR-4) cucurbits/ EPA requirement re: analytical ref standards at EPA Repository

Hi Tom,

As you requested, I created a letter regarding our request for a waiver of the requirement to send an analytical reference standard for the 8,9-Z B1b isomer of emamectin to the EPA Repository. The letter includes the information and discussion in my 9-11-2012 e-mail below.

From: Thomas Harris [<mailto:harris.thomas@epamail.epa.gov>]

Sent: Tuesday, October 02, 2012 3:36 PM

To: Brinkley Carolyn USGR

Subject: Fw: Analytical reference standards for emamectin benzoate are needed.

Importance: High

Carolyn,

Thanks for taking care of the emamectin reference standard.

Regarding the waiver request for the metabolites, I need to do this with more official tracking and get a written memo response from HED. Please send me a letter on Syngenta letterhead with the request. Copy/paste from your note below to get the basic text and then edit a bit. Just email me a .pdf of the cover letter and I'll take care of the tracking. If we can wrap this up before the 10/25/12 due date for new cucurbits and ornamentals that would be great but not absolutely critical.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit <http://www.epa.gov/pesticides>

--- Forwarded by Thomas Harris/DC/USEPA/US on 10/02/2012 03:28 PM ---

From: Nancy Dodd/DC/USEPA/US
To: Thomas Harris/DC/USEPA/US@EPA
Cc: Steve Funk/DC/USEPA/US@EPA, Leung Cheng/DC/USEPA/US@EPA, Meheret Negussie/DC/USEPA/US@EPA, Amelia Acierto/DC/USEPA/US@EPA
Date: 10/02/2012 02:32 PM
Subject: Re: Fw: Analytical reference standards for emamectin benzoate are needed.

I think an official paper request tracked in OPPIN would be a good way to document the issue for future reference.

Thomas Harris---10/02/2012 12:49:33 PM---Nancy, Cleaning my emails from when I was on vacation. This one is asking for a waiver to supply an

From: Thomas Harris/DC/USEPA/US
To: Nancy Dodd/DC/USEPA/US@EPA
Cc: Jeff Dawson/DC/USEPA/US@EPA
Date: 10/02/2012 12:49 PM
Subject: Fw: Analytical reference standards for emamectin benzoate are needed.

Nancy,

Cleaning my emails from when I was on vacation. This one is asking for a waiver to supply an analytical reference standard for a metabolite that you had asked for.

>>> Question: what is the proper way to request this waiver? I think we probably need an official paper request tracked in OPPIN (I might be able to create it from this email) with a DP to HED for an official memo response. What do you think?

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit <http://www.epa.gov/pesticides>

--- Forwarded by Thomas Harris/DC/USEPA/US on 10/02/2012 12:46 PM ---

From: <carolyn.brinkley@syngenta.com>
To: Thomas Harris/DC/USEPA/US@EPA
Date: 09/11/2012 04:13 PM
Subject: RE: FW: Analytical reference standards for emamectin benzoate are needed.

E-FILE: emamectin petition for tolerance cucurbits - EPA requirement to submit analytical reference standards

Hi Tom,

Responding to your message regarding the pending IR-4 petition for an emamectin tolerance in/on cucurbits and analytical standards for emamectin.

Nancy Dodd said, in her e-mail to Barbara Madden below, that we need to send the following to Theresa Cole at the EPA Repository Analytical Chemistry Lab in Fort Meade.:

1. An updated certificate of analysis or a new analytical reference standard for the emamectin 8,9-Z isomer of B1a (NOA 438376)
2. Analytical reference standards for MFB1a (NOA415692) and 8,9-Z B1b.

RESPONSE

1. DONE: We sent an updated certificate of analysis for the emamectin isomer standard to Theresa Cole. (I'll look for written documentation - may just be an e-mail)
2. WAIVER REQUEST: We can't provide the requested standards for MFB1a (NOA415692) and 8,9-Z B1b and are requesting a waiver of this requirement for several reasons. Details follow.

I forwarded the request for these analytical standards to my Syngenta colleague who manages analytical standards.

- He said no one to his knowledge has ever produced analytical reference standards for these metabolites.
- Since Merck was the original registrant of emamectin, he decided to look into the analytical history for emamectin with respect to the tolerances and registrations EPA approved for emamectin when Merck was the registrant.
 - o Here's what he found and the basis for our request to waive the requirement to provide these particular analytical reference standards to the Repository

The original enforcement method submitted by Merck was an HPLC Fluorescence detection method which is available from EPA online. This method does not resolve the 8,9Z isomers from the parent isomers, so B1a coelutes with 8,9Z B1a and it's the same for B1b. For validation, Merck fortified with an 8,9Z B1a standard + B1a parent and by extension Merck claimed that B1b should behave similarly. So it appears Merck never produced a 8,9Z B1b standard and because Merck did not resolve the Z isomers in their analysis EPA just set the tolerance limits based on the sums of the Z+parent components.

The Novartis/Syngenta analytical method was validated with only the 8,9Z B1a isomer as well; we've never produced the 8,9Z B1b standard either. In all of the storage stability studies and in everything else we have submitted to the EPA for emamectin we have only analyzed for the 8,9Z B1a isomer. And our current method clearly indicates that we're analyzing only for 8,9Z B1a. All of the other metabolites in the tolerance expression are listed as B1a isomers only. So it appears that only the 8,9Z standard singles out inclusion of B1b in the tolerance expression. This is presumably due to the original petition from Merck in which they could not distinguish the Z isomers from parent in their analytical method. We believe the original metabolism shows how little 8,9Z B1b would be seen in a typical residue profile given that the AI itself only has ~5% of B1b.

PLEASE LET ME KNOW IF OUR WAIVER REQUEST IS ACCEPTABLE

From: Thomas Harris [<mailto:harris.thomas@epamail.epa.gov>]
Sent: Thursday, August 02, 2012 12:24 PM
To: Brinkley Carolyn USGR
Cc: Parshley Tom USGR
Subject: Fw: Analytical reference standards for emamectin benzoate are needed.

Carolyn,

Can you take care of this before October? I don't want to have to deal with it in an acceptance letter; much easier to resolve beforehand. I'm assuming this is fairly simply but feel free to correct me!

Assuming you can easily resolve this, please cc me on the correspondence sent to the Fort Meade lab (a copy sent by email would be great) so I can show it's resolved before we get to stamping the label.

Tom Harris
 EPA/OPPTS/OPP/RD/IRB
 voice: (703) 308-9423
 fax: (703) 308-0029
harris.thomas@epa.gov
 visit <http://www.epa.gov/pesticides>

— Forwarded by Thomas Harris/DC/USEPA/US on 08/02/2012 12:19 PM —

From: Barbara Madden/DC/USEPA/US
 To: Thomas Harris/DC/USEPA/US@EPA
 Cc: John Hebert/DC/USEPA/US@EPA, Andrew Ertman/DC/USEPA/US@EPA
 Date: 08/02/2012 11:55 AM
 Subject: Fw: Analytical reference standards for emamectin benzoate are needed.

Tom,

I imagine this could be a condition of registration? Or is this no longer allowed to be a condition? Something

you may want to share with the registrant because if this cannot be a condition we are not going to make an October date unless they satisfy this. Let me know. Thanks Barbara

— Forwarded by Barbara Madden/DC/USEPA/US on 08/02/2012 11:52 AM —

From: Nancy Dodd/DC/USEPA/US

To: Barbara Madden/DC/USEPA/US@EPA, Andrew Ertman/DC/USEPA/US@EPA

Date: 08/02/2012 10:54 AM

Subject: Analytical reference standards for emamectin benzoate are needed.

IR-4 has a petition on cucurbits. Analytical reference standards need to be sent to the repository as stated below.

- **The standard for emamectin 8,9-Z isomer of B1a (NOA 438376) expired on 3/31/2012. An updated certificate of analysis or a new analytical reference standard must be provided to the EPA National Pesticide Standards Repository.**
- **Analytical reference standards for MFB1a (NOA415692) and 8,9-Z B1b are currently unavailable at the Repository. Analytical reference standards must be provided.**

The new standards should be sent to the Analytical Chemistry Lab, which is located at Fort Meade, to the attention of Theresa Cole at the following address:

USEPA
National Pesticide Standards Repository/Analytical Chemistry Branch/OPP
701 Mapes Road
Fort George G. Meade, MD 20755-5350

(Note that the mail will be returned if the extended zip code is not used.)

Nancy Dodd

This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.

This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.

This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.

Decision Information for 100-1270

Decision Seq: 473081 Action Code: 575, CONDITIONAL REGISTRATION FOLLOW-UP; DATA REQUIRE ...

FFS Start Date: Tentative Ind: No Start/Stop Clock FGPA Clock:

Due Date: 12-Feb-2013 75-Day Due Date: Days Elapsed:

OPP Target Due Date: 21-Day Due Date: FFS Original Decision: ...

Negotiated Due Date: 45/90 Due Date:

Registrant Response Due Date: Predecisional Due Date:

Current Status: COMPLETED (29-Jan-2013)

75 Day Letters 45/90 Day Screen Primary Decisions

FFS Negotiated Due Dates OPP Target Due Date Decision Comments Payment Unmatched Payments

Decision Ownership Receipts Data Package Reduced Risk Meetings & Milestones FFS Information

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S: 925989	Harris, Thomas	100-1270	12-Feb-2013	GENERAL RESPONSE TO APPLICAT

immunotox study; turned over to PRD to track under reg review

Viewing Record 1 of 1

Immunotox study -

- Sent to RD but not connected to a registration action*
- turned over to PRD to track under registration review since this was sent in response to DCI*

*- T Harris
RD/IRB
1/29/2013*



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 2, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-452134
EPA File Symbol or Registration Number: 100-1270
Product Name: EMAMECTIN BENZOATE TECHNICAL II
EPA Application Receipt Date: 15-Jul-2011
EPA Waiver Request Receipt Date: 15-Jul-2011
EPA Company Number: 100
Company Name: SYNGENTA CROP PROTECTION, LLC

BUNNIE KONAT
SYNGENTA CROP PROTECTION, LLC
D/B/A SYNGENTA CROP PROTECTION, INC.
PO Box 18300
GREENSBORO, NC 27419-8300

SUBJECT: Fee Exemption

Dear Registrant:

The Office of Pesticide Programs has determined that the exemption in section 33(b)(7)(E) (exempting IR-4) of the Federal Insecticide, Fungicide, and Rodenticide Act applies to this action. Accordingly, there is no fee associated with the above referenced action. The decision review period for this action begins on the date of this letter.

The Action has been identified as Action Code: R170.3

NEW USE;EACH ADDITIONAL NEW FOOD USE;THREE NEW USES;

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Oscar Morales, Director
Information Technology & Resources Management Division
Office of Pesticide Programs



Syngenta Crop Protection, LLC
P.O. Box 18300
Greensboro, NC 27419-8300
www.syngenta.com

FedEx

March 8, 2011

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Mr. John Hebert, PM 7, IRB

SUBJECT: EMAMECTIN BENZOATE TECHNICAL II
EPA REG. NO. 100-1270
SUBMISSION OF FINAL PRINTED LABELING

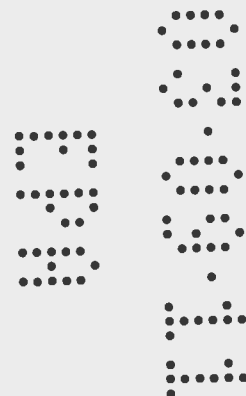
Syngenta Crop Protection, LLC is submitting one copy of final printed labeling for Emamectin Benzoate Technical II that reflects the labeling accepted in EPA's approval letter dated August 8, 2010. This approval is in response to a Notification for Pesticide Registration Notice (PRN) 2007-4. The Storage and Disposal section of the label has been highlighted to show the changes made by PRN 2007-4.

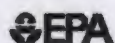
Also enclosed is EPA Form 8570-1 indicating submission of final printed labeling. If you have any questions, please contact me at 336-632-5927. Thank you.

Sincerely,

Patsy Laird
Regulatory Label Specialist
Regulatory Affairs

Enclosures





United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 100-1270	2. EPA Product Manager John Hebert	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Emamectin Benzoate Technical II	PM# 7, IRB	
5. Name and Address of Applicant (Include ZIP Code) Syngenta Crop Protection, LLC P. O. Box 18300 Greensboro, NC 27419 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated <u>August 9, 2010</u>
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Syngenta Crop Protection, LLC is submitting one copy of final printed labeling for Emamectin Benzoate Technical II that reflects the labeling accepted in EPA's approval letter dated August 9, 2010. This approval is in response to a Notification for Pesticide Registration Notice (PRN) 2007-4. The Storage and Disposal section of the label has been highlighted to show the changes made by PRN 2007-4.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
*Certification must be submitted		If "Yes" Unit Packaging wgt. No. per Container	If "Yes" Unit Packaging wgt. No. per container	<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 27 lb. 9 oz.		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other <u>Pressure Sensitive</u>	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Patsy Laird		Title Regulatory Label Specialist		Telephone No. (Include Area Code) 336-632-5927	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.				6. Date Application Received (Stamped)	
2. Signature <i>Patsy Laird</i>		3. Title Regulatory Label Specialist, Regulatory Affairs			
4. Typed Name Patsy Laird		5. Date March 8, 2011			

Emamectin Benzoate Technical II

An insecticide for formulation into end-use insecticide products intended for non-domestic terrestrial outdoor food use.

Active Ingredient:	
Emamectin Benzoate (CAS No. 155569-91-8)	97.0%
Other Ingredients:	3.0%
Total:	100.0%

KEEP OUT OF REACH OF CHILDREN WARNING/AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use on label.

EPA Reg. No. 100-1270 EPA Est. 70992-CHN109
Product of China

Product ID:

34798

AUG - 8 2010

27 pounds, 9 ounces
(12.5 kg)

Net Weight

FIRST AID	
If swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If inhaled	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth, if possible.• Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN

Probably mucosal damage may contraindicate the use of gastric lavage. Early signs of intoxication include dilated pupils, muscular incoordination, and muscle tremors. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements.

In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

HOT LINE NUMBER

For 24-Hour Medical Emergency Assistance (Human or Animal) or
Chemical Emergency Assistance (Spill, Leak, Fire, or Accident),
Call
1-800-888-8372

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING/AVISO

May be fatal if inhaled or swallowed. Causes moderate eye irritation. Harmful if absorbed through skin. Do not breathe dust. Avoid contact with skin, eyes, or clothing. The following protective clothing must be worn during all handling and formulation operations: airline mask or air supplied hood, chemical-resistant goggles and gloves, full body garments with shoe protectors and head cover. Disposable clothing is recommended. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

Environmental Hazards

This pesticide is toxic to fish, birds, mammals, and aquatic invertebrates. Do not discharge effluent containing this active ingredient into lakes, streams, ponds, estuaries, oceans, or other public waters, unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit, and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, LLC or Seller. To the extent permitted by applicable law, Buyer and Seller agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA and Seller warrant that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use. Subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions, or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and (2) Buyer and User assume the risk of any such use. TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Instructions to Formulators: Formulators using this product are responsible for obtaining Environmental Protection Agency registration for their formulated products.

This technical product may be used only for formulation of end-use insecticides for the uses listed below:

Agricultural crops (Terrestrial Food Crops):

- Brassica leafy vegetables crop group 5
- Cotton
- Fruiting vegetables (except cucurbits) crop group 8
- Leafy vegetables (except Brassica) crop group 4
- Pome fruit crop group 11
- Tree nuts crop group 14 plus pistachios
- Tobacco
- Turnip greens (tops, leaves)*

*For use on turnip varieties grown for leaves only. Do not use on turnip varieties grown for roots or dual-purpose varieties grown for roots and leaves.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in a tightly closed original container in a cool, dry place. Do not store near food or feed.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Handling

Bags: Non-refillable container. Do not reuse or refill this container. Completely empty bag into formulation equipment. Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

Fiber Drums with Liners: Non-refillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. Then offer for recycling if available or dispose of liner in a sanitary landfill or by incineration. If drum is contaminated and cannot be reused, dispose of it in a manner required by its liner.

CONTAINER IS NOT SAFE FOR FOOD, FEED, OR DRINKING WATER.

Note: For minor spills, leaks, etc. follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during clean-up and disposal of wastes.

©2011 Syngenta

For non-emergency
(e.g. current product information)
call Syngenta Crop Protection, LLC
at 1-800-334-9481

Manufactured for:
Syngenta Crop Protection, LLC
P.O. Box 18300
Greensboro, NC 27419-8300
SCP 1270A-L1B 0810

Issued 01.2011

Material to be added to an e-Jacket/Jacket

Reg. # 100-1270

Decision # 436591

Description: Notification 2007-4

Container handling

1. Placement within the e-Jacket/jacket:

☒ Default: (chronological, top = newest)

☐ File Location: (eg. "before page 45 in .pdf")

2. ☒ Send to Data Extraction contractors this material:

☐ Newly stamped accepted label

☒ Notification

☐ New CSF

☐ Other: _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Tom Harris

Phone: 308-9423

Division: RD

Date: 8/9/10



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

8/9/2010

Carolyn Brinkley
Syngenta Crop Protection, Inc.
PO Box 18300
Greensboro, NC 27419

Subject: Label Notification(s) for Pesticide Registration Notices 2007-4

Dear Ms. Brinkley:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4 (revised April 29, 2008) for:

**EPA Registration 100-1270
Emamectin Benzoate Technical II
submitted 6/22/2010 (D# 436591)**

The Registration Division (RD) has conducted a review of this request for applicability under PRN 2007-4 and finds that the label change(s) requested falls within the scope of PRN-2007-4. The label has been date-stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on nonrefillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

Sincerely yours,

A handwritten signature in black ink, appearing to be "LS" or "LS/".

Thomas C. Harris
Biologist
Insecticide Rodenticide Branch
Registration Division (7505P)
Harris.Thomas@epa.gov
(703) 308-9423

Emamectin Benzoate Technical II

An insecticide for formulation into end-use insecticide products intended for non-domestic terrestrial outdoor food use.

Active Ingredient:

Emamectin Benzoate (CAS No. 155569-91-8)..... 97.0%

Other Ingredients: 3.0%

Total: 100.0%

KEEP OUT OF REACH OF CHILDREN

WARNING/AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use on label.

EPA Reg. No. 100-1270

EPA Est. xxxxx

Product of xxxxx

Product ID. xxxx

SCP 1270A-M(NOTIF)

NOTIFICATION

AUG 09 2010

Net Weight

FIRST AID	
If swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth, if possible. • Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
<p align="center">NOTE TO PHYSICIAN</p> <p>Probably mucosal damage may contraindicate the use of gastric lavage. Early signs of intoxication include dilated pupils, muscular incoordination, and muscle tremors. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements.</p> <p>In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.</p>	
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p>	
<p align="center">HOT LINE NUMBER</p> <p align="center">For 24 Hour Medical Emergency Assistance (Human or Animal) or Chemical Emergency Assistance (Spill, Leak, Fire, or Accident), Call 1-800-888-8372</p>	

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING/AVISO

May be fatal if inhaled or swallowed. Causes moderate eye irritation. Harmful if absorbed through skin. Do not breathe dust. Avoid contact with skin, eyes, or clothing. The following protective clothing must be worn during all handling and formulation operations: airline mask or air supplied hood, chemical-resistant goggles and gloves, full body garments with shoe protectors and head cover. Disposable clothing is recommended. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

Environmental Hazards

This pesticide is toxic to fish, birds, mammals, and aquatic invertebrates. Do not discharge effluent containing this active ingredient into lakes, streams, ponds, estuaries, oceans, or other public waters, unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit, and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, Inc. or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and, (2) Buyer and User assume the risk of any such use. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.**

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Instructions to Formulators

Formulators using this product are responsible for obtaining Environmental Protection Agency registration for their formulated products.

This technical product may be used only for formulation of end-use insecticides for the uses listed below:

Agricultural crops (Terrestrial Food Crops):

- *Brassica* leafy vegetables crop group 5
- Cotton
- Fruiting vegetables (except cucurbits) crop group 8
- Leafy vegetables (except *Brassica*) crop group 4
- Pome fruit crop group 11
- Tree nuts crop group 14 plus pistachios
- Tobacco
- Turnip greens (tops, leaves)*

*For use on turnip varieties grown for leaves only. Do not use on turnip varieties grown for roots or dual-purpose varieties grown for roots and leaves.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage

Store in a tightly closed original container in a cool, dry place. Do not store near food or feed.

Pesticide Disposal

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.


Container Handling

Bags: Non-refillable container. Do not reuse or refill this container. Completely empty bag into formulation equipment. Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

Fiber Drums with Liners: Non-refillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. Then offer for recycling if available or dispose of liner in a sanitary landfill or by incineration. If drum is contaminated and cannot be reused, dispose of it in a manner required by its liner.

CONTAINER IS NOT SAFE FOR FOOD, FEED, OR DRINKING WATER.

Note: For minor spills, leaks, etc. follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during clean up and disposal of wastes.

The Syngenta logo and the CP FRAME  are trademarks of a Syngenta Group Company.

©2009 Syngenta

For non-emergency (e.g. current product information)
call Syngenta Crop Protection, Inc. at 1-800-334-9481

Manufactured for:
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, North Carolina 27419-8300

SCP 1270A-M(NOTIF)

EmaBenzTech II 1270A-M(NOTIF) PRN 2007-4 JUN2010 CLEAN – pl –6/21/10
000100-01270.20100621.EMA-BENZ-TECH-II_PRN2007-4_JUN2010.pdf

Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419-8300
www.syngenta.com



FedEx

June 22, 2010

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Ms. Linda Arrington

SUBJECT: EMAMECTIN BENZOATE TECHNICAL II
EPA REG. NO. 100-1270
NOTIFICATION OF LABEL CHANGE PER PR NOTICE 2007-4

Syngenta Crop Protection, Inc. is submitting Notification for Emamectin Benzoate Technical II, EPA Reg. No. 100-1270. Syngenta is amending the Storage and Disposal section of the label by Notification according to the directions stated in PR Notice 2007-4.

Attached are:

- One copy of the label with the changes clearly marked
- One unmarked copy of the label
- A CD of the unmarked copy of the label for "Electronic Comparison and Review"
- Certificate with Respect to Label Integrity Form
- Completed EPA Form 8570-1

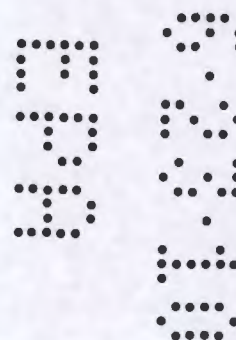
Thank you in advance for approving this Notification. If you have any questions, please contact me at 336-632-2494.

Sincerely,

A handwritten signature in cursive script that reads "Pat Dinnen".

Pat Dinnen
Label Group Leader
Regulatory Affairs

Enclosures





United States
Environmental Protection Agency
 Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Notification**Application for Pesticide - Section I**

1. Company/Product Number 100-1270	2. EPA Product Manager John Hebert	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Emamectin Benzoate Technical II	PM# 7	
5. Name and Address of Applicant (Include ZIP Code) Syngenta Crop Protection, Inc. P. O. Box 18300 Greensboro, NC 27419 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

- ☐ Amendment - Explain below. ☐ Final printed labels in response to Agency letter dated _____
- ☐ Resubmission in response to Agency letter dated _____ ☐ "Me Too" Application.
- ☒ Notification - Explain below. ☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.).

Notification of label change per PR Notice 2007-4. This Notification is consistent with the guidance of PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§156.10, 156.140, 156.144 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Syngenta is amending the Storage and Disposal section of the label by Notification according to the directions stated in PR Notice 2007-4.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
*Certification must be submitted				<input checked="" type="checkbox"/> Plastic	
If "Yes" No. per Unit Packaging wgt. Container		If "Yes" No. per Unit Packaging wgt. container		<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 27.5 lb.		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			
		<input checked="" type="checkbox"/> Other <u>Pressure Sensitive</u>			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Pat Dinnen		Title Label Group Leader		Telephone No. (Include Area Code) 336-632-2494	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.				6. Date Application Received (Stamped)	
2. Signature <i>Pat Dinnen</i>		3. Title Regulatory Specialist			
4. Typed Name Pat Dinnen		5. Date June 22, 2010			

Certification with Respect to Label Integrity

Version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
100-1270	6/22/2010	000100-01270.20100621.EMA-BENZ-TECH-II_PRN2007-4_JUN2010.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Pat Dinnen

Signature

June 22, 2010

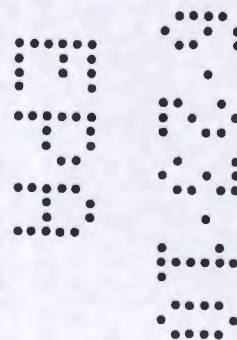
Date

Pat Dinnen

Name (typed)

Label Group Leader

Title



Eamectin Benzoate Technical II

An insecticide for formulation into end-use insecticide products intended for non-domestic terrestrial outdoor food use.

Active Ingredient:

Eamectin Benzoate (CAS No. 155569-91-8)97.0%

Other Ingredients:3.0%

Total:.....100.0%

KEEP OUT OF REACH OF CHILDREN

WARNING/AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use on label.

EPA Reg. No. 100-1270

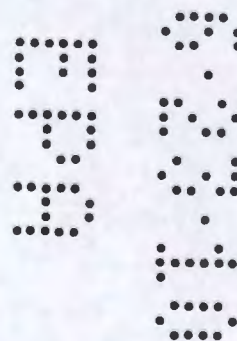
EPA Est. xxxxx

Product of xxxxx

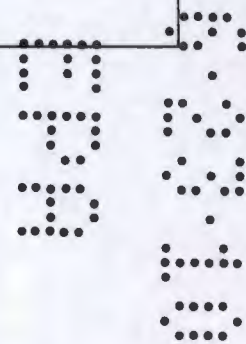
Product ID. xxxx

SCP 1270A-M(NOTIF)

Net Weight



FIRST AID	
If swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth, if possible. • Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
<p align="center">NOTE TO PHYSICIAN</p> <p>Probably mucosal damage may contraindicate the use of gastric lavage. Early signs of intoxication include dilated pupils, muscular incoordination, and muscle tremors. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements.</p> <p>In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.</p>	
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p>	
<p align="center">HOT LINE NUMBER</p> <p align="center">For 24 Hour Medical Emergency Assistance (Human or Animal) or Chemical Emergency Assistance (Spill, Leak, Fire, or Accident), Call 1-800-888-8372</p>	



PRECAUTIONARY STATEMENTS

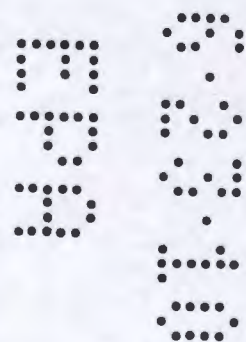
Hazards to Humans and Domestic Animals

WARNING/AVISO

May be fatal if inhaled or swallowed. Causes moderate eye irritation. Harmful if absorbed through skin. Do not breathe dust. Avoid contact with skin, eyes, or clothing. The following protective clothing must be worn during all handling and formulation operations: airline mask or air supplied hood, chemical-resistant goggles and gloves, full body garments with shoe protectors and head cover. Disposable clothing is recommended. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

Environmental Hazards

This pesticide is toxic to fish, birds, mammals, and aquatic invertebrates. Do not discharge effluent containing this active ingredient into lakes, streams, ponds, estuaries, oceans, or other public waters, unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit, and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.



CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

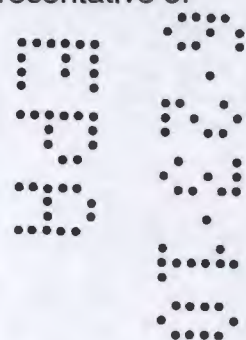
NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, Inc. or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and, (2) Buyer and User assume the risk of any such use. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.**

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.



DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Instructions to Formulators

Formulators using this product are responsible for obtaining Environmental Protection Agency registration for their formulated products.

This technical product may be used only for formulation of end-use insecticides for the uses listed below:

Agricultural crops (Terrestrial Food Crops):

- *Brassica* leafy vegetables crop group 5
- Cotton
- Fruiting vegetables (except cucurbits) crop group 8
- Leafy vegetables (except *Brassica*) crop group 4
- Pome fruit crop group 11
- Tree nuts crop group 14 plus pistachios
- Tobacco
- Turnip greens (tops, leaves)*

*For use on turnip varieties grown for leaves only. Do not use on turnip varieties grown for roots or dual-purpose varieties grown for roots and leaves.

STORAGE AND DISPOSAL

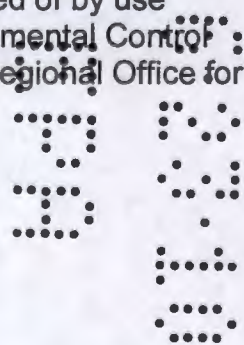
Do not contaminate water, food, or feed by storage **and/or** disposal.

Pesticide Storage

Store in a tightly closed original container in a cool, dry place. Do not store near food or feed.

Pesticide Disposal

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.



Container Disposal

Bulk

Thoroughly clean container before reuse. Consult Federal, state, or local disposal authorities for approved alternative procedures.

250-Gal. Mini Bulk

This is a refillable container that must be returned to an authorized Syngenta refilling facility for refilling or disposal. Before refilling, inspect thoroughly for damage such as cracks, punctures, bulges, dents, abrasions, and damaged or worn threads on closure devices. After filling and before transporting, check for leaks. Do not refill or transport damaged or leaking container.


Other Containers Handling

Bags: Non-refillable container. Do not reuse or refill this container. Completely empty bag into formulation equipment. Triple-rinse (or equivalent). Then offer for recycling if available or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration other procedures approved by state and local authorities.

Fiber Drums with Liners: Non-refillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. Then offer for recycling if available or dispose of liner in a sanitary landfill or by incineration. If drum is contaminated and cannot be reused, dispose of it in a manner required by its liner.

CONTAINER IS NOT SAFE FOR FOOD, FEED, OR DRINKING WATER.

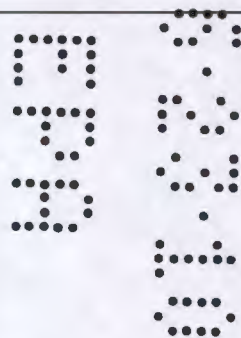
Note: For minor spills, leaks, etc. follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during clean up and disposal of wastes.

The Syngenta logo and the CP FRAME  are trademarks of a Syngenta Group Company.

©2009 Syngenta

For non-emergency (e.g. current product information)
call Syngenta Crop Protection, Inc. at 1-800-334-9481

Manufactured for:
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, North Carolina 27419-8300



SCP 1270A-M(NOTIF)

EmaBenzTech II 1270A-M(NOTIF) PRN 2007-4 JUN2010 – pl –6/21/10

93E100

Material to be added to an e-Jacket/Jacket

Reg. # 100-1270 Decision #

Description: FPL **NOT REVIEWED**
In Accordance with PR Notice 82-2
Based on Draft Labeling Dated 5/7/2009

1. Placement within the e-Jacket/jacket:

- ☒ Default: (chronological, top = newest)
☐ File Location: (eg. "before page 45 in .pdf")

2. ☐ Send to Data Extraction contractors this material:

- ☐ Newly stamped accepted label
☐ Notification
☐ New CSF
☐ Other: _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Tom Harris

Phone: 308-9423

Division: RD

Date: JAN 27 2010



Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419-8300
www.syngenta.com

June 22, 2008

Document Processing Desk(FPL)
Office of Pesticide Programs (H7504P)
Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

ATTN: Mr. Thomas C. Harris IRB

SUBJECT: Eamectin Benzoate Technical II EPA REG. NO. 100-1270
Submission of Final Printed Version of Labeling to Comply with
EPA Approval Letter Dated May 7, 2009.

Dear: Mr. Harris:

Syngenta Crop Protection, Inc. hereby submits 2 copies of final printed version of labeling for Eamectin Benzoate Technical II (EPA Reg. No. 100-1270) as required in EPA approval letter dated May 7, 2009. As per Agency letter, in the Directions for Use, "14" has been added to the tree nut statement to read "Tree nuts crop group 14 plus pistachios".

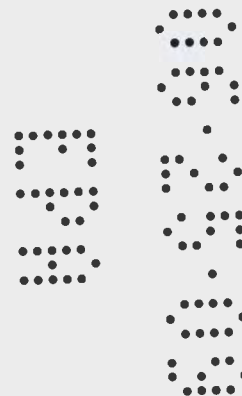
The label copy code is SCP 1270A-L2A 0509.


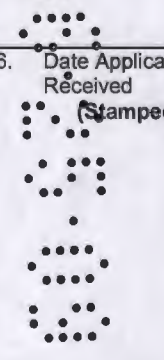
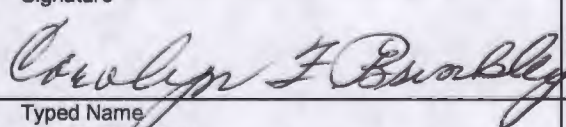
We trust that you will find this submission in order; however, should you have any questions, please contact me at 336.632-2838.

Sincerely,


Sr. Regulatory Product Manager/NAFTA Insecticides
Regulatory Affairs

Enclosures: 2 copies of final printed labeling
EPA form 8570-1



 United States Environmental Protection Agency Washington, DC 20460		<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide - Section I			
1. Company/Product Number 100-1270		2. EPA Product Manager Thomas C. Harris	
4. Company/Product (Name) Emamectin Benzoate Technical II		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Syngenta Crop Protection, Inc. P. O. Box 18300 Greensboro, NC 27419 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
Section - II			
<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.		<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated <u>May 7, 2009</u> <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.	
1. Explanation: Use additional page(s) if necessary. (For Section I and Section II.) Syngenta Crop Protection, Inc. hereby submits 2 copies of final printed version of labeling for Emamectin Benzoate Technical II (EPA Reg. No. 100-1270) as required in EPA approval letter dated May 7, 2009. As per Agency letter, in the Directions for Use, "14" has been added to the tree nut statement to read "Tree nuts crop group 14 plus pistachios". The label copy code is SCP 1270A-L2A 0509.			
Section - III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No <i>*Certification must be submitted</i>	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per Container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	
		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			
Section - IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Carolyn F. Brinkley		Title Sr. Regulatory Product Manager/NAFTA Insecticides Regulatory Affairs Telephone No. (Include Area Code) (336) 632- 2838	
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped) 	
2. Signature 		3. Title Sr. Regulatory Product Manager/NAFTA Insecticides Regulatory Affairs	
4. Typed Name Carolyn F. Brinkley		5. Date June 22, 2009	

Emamectin Benzoate Technical II

An insecticide for formulation into end-use insecticide products intended for non-domestic terrestrial outdoor food use.

Active Ingredient:	
Emamectin Benzoate (CAS No. 155569-91-8)	97.0%
Other Ingredients:	3.0%
Total:	100.0%

KEEP OUT OF REACH OF CHILDREN WARNING/AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use on label.

EPA Reg. No. 100-1270

EPA Est. 84716-CHN-001

Product of China

Product ID. **38134**

27 pounds, 9 ounces (12.5 kg)
Net Weight

NOT REVIEWED
In Accordance with PR Notice 82-2
Based on Draft Labeling Dated

5/7/2009



Emamectin Benzoate Technical II

FIRST AID	
If swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If inhaled	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth, if possible.• Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
NOTE TO PHYSICIAN <p>Probably mucosal damage may contraindicate the use of gastric lavage.</p> <p>Early signs of intoxication include dilated pupils, muscular incoordination, and muscle tremors. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements.</p> <p>In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.</p> <p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p>	
HOT LINE NUMBER <p>For 24 Hour Medical Emergency Assistance (Human or Animal) or Chemical Emergency Assistance (Spill, Leak, Fire, or Accident), Call 1-800-888-8372</p>	

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING/AVISO

May be fatal if inhaled or swallowed. Causes moderate eye irritation. Harmful if absorbed through skin. Do not breathe dust. Avoid contact with skin, eyes, or clothing. The following protective clothing must be worn during all handling and formulation operations: airline mask or air supplied hood, chemical-resistant goggles and gloves, full body garments with shoe protectors and head cover. Disposable clothing is recommended. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

Environmental Hazards

This pesticide is toxic to fish, birds, mammals, and aquatic invertebrates. Do not discharge effluent containing this active ingredient into lakes, streams, ponds, estuaries, oceans, or other public waters, unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit, and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, Inc. or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

Emamectin Benzoate Technical II

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and, (2) Buyer and User assume the risk of any such use. TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Instructions to Formulators

Formulators using this product are responsible for obtaining Environmental Protection Agency registration for their formulated products.

This technical product may be used only for formulation of end-use insecticides for the uses listed below:

Agricultural crops (Terrestrial Food Crops):

- Brassica leafy vegetables crop group 5
- Cotton
- Fruiting vegetables (except cucurbits) crop group 8
- Leafy vegetables (except Brassica) crop group 4
- Pome fruit crop group 11
- Tree nuts crop group 14 plus pistachios
- Tobacco
- Turnip greens (tops, leaves)*

*For use on turnip varieties grown for leaves only. Do not use on turnip varieties grown for roots or dual-purpose varieties grown for roots and leaves.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage

Store in a tightly closed original container in a cool, dry place. Do not store near food or feed.

Pesticide Disposal

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal

Bulk: Thoroughly clean container before reuse. Consult Federal, state, or local disposal authorities for approved alternative procedures.

Mini Bulk: This is a refillable container that must be returned to an authorized Syngenta refilling facility for refilling or disposal. Before refilling, inspect thoroughly for damage such as cracks, punctures, bulges, dents, abrasions, and damaged or worn threads on closure devices. After filling and before transporting, check for leaks. Do not refill or transport damaged or leaking container.

Other Containers: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

CONTAINER IS NOT SAFE FOR FOOD, FEED, OR DRINKING WATER.

Note: For minor spills, leaks, etc. follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during clean up and disposal of wastes.

©2009 Syngenta

For non-emergency (e.g. current product information)
call Syngenta Crop Protection, Inc. at 1-800-334-9481

Manufactured for:
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, North Carolina 27419-8300

SCP 1270A-L2A 0509



Material to be added to an e-Jacket/Jacket

Reg. No. 100-1270

Description: add tree nuts

1. ☒ Placement within the e-Jacket/jacket:

☒ Default: (chronological, top = newest)

☒ File Location: (PDF page number, i.e., "before page 45")

2. ☒ Send to Data Extraction contractors this material:

☒ Newly stamped accepted label

☐ Notification

☐ New CSF

☐ Other: _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: Tom Harris

Phone: 308-9423 Division: RD

Date: 5/7/09



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

5/7/2009

Carolyn Brinkley
Syngenta Crop Protection, Inc.
PO Box 18300
Greensboro, NC 27419

Subject: Eamectin Benzoate Technical II, EPA Reg. # 100-1270
label amendment submitted 4/9/2009
accepted with comments

Dear Ms. Brinkley:

This label amendment adds a new use on tree nuts crop group 14 and pistachios. The revised labeling submitted in connection with the registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is conditionally acceptable provided you:

1. In the Directions for Use, add "14" so the new text reads "Tree nuts crop group 14 plus pistachios."
2. Submit two copies of the final printed label before you release the product for shipment.

If the above provisions are not complied with the registration will be subject to cancellation in accordance with FIFRA Section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A copy of the label stamped "accepted with comments" is enclosed for your records.

Sincerely yours,

151

Thomas C. Harris
Insecticide / Rodenticide Branch
Registration Division (7505C)
Office of Pesticide Programs
harris.thomas@epa.gov
(703) 308-9423

enclosure

Eamectin Benzoate Technical II

An insecticide for formulation into end-use insecticide products intended for non-domestic terrestrial outdoor food use.

Active Ingredient:

Eamectin Benzoate (CAS No. 155569-91-8)..... 97.0%

Other Ingredients: 3.0%

Total: 100.0%

KEEP OUT OF REACH OF CHILDREN

WARNING/AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use on label.

EPA Reg. No. 100-1270

EPA Est. xxxxx

Product of xxxxx

Product ID. xxxx

SCP 1270A-M(draft treenuts)

Net Contents

**ACCEPTED
With COMMENTS
In EPA Letter Dated:**

MAY - 7 2009

**Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:**

100-1270

000100-01270.20090305.treenuts.pdf

FIRST AID	
If swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth, if possible. • Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
<p align="center">NOTE TO PHYSICIAN</p> <p>Probably mucosal damage may contraindicate the use of gastric lavage. ✖</p> <p>Early signs of intoxication include dilated pupils, muscular incoordination, and muscle tremors. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements.</p> <p>In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.</p>	
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p>	
<p align="center">HOT LINE NUMBER</p> <p align="center">For 24 Hour Medical Emergency Assistance (Human or Animal) or Chemical Emergency Assistance (Spill, Leak, Fire, or Accident), Call 1-800-888-8372</p>	

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals**WARNING/AVISO**

May be fatal if inhaled or swallowed. Causes moderate eye irritation. Harmful if absorbed through skin. Do not breathe dust. Avoid contact with skin, eyes, or clothing. The following protective clothing must be worn during all handling and formulation operations: airline mask or air supplied hood, chemical-resistant goggles and gloves, full body garments with shoe protectors and head cover. Disposable clothing is recommended. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

Environmental Hazards

This pesticide is toxic to fish, birds, mammals, and aquatic invertebrates. Do not discharge effluent containing this active ingredient into lakes, streams, ponds, estuaries, oceans, or other public waters, unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit, and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, Inc. or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and, (2) Buyer and User assume the risk of any such use. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.**

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Instructions to Formulators

Formulators using this product are responsible for obtaining Environmental Protection Agency registration for their formulated products.

This technical product may be used only for formulation of end-use insecticides for the uses listed below:

Agricultural crops (Terrestrial Food Crops):

- *Brassica* leafy vegetables crop group 5
- Cotton
- Fruiting vegetables (except cucurbits) crop group 8
- Leafy vegetables (except *Brassica*) crop group 4
- Pome fruit crop group 11
- Tree nuts crop group plus pistachios
- Tobacco
- Turnip greens (tops, leaves)*

*For use on turnip varieties grown for leaves only. Do not use on turnip varieties grown for roots or dual-purpose varieties grown for roots and leaves.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage

Store in a tightly closed original container in a cool, dry place. Do not store near food or feed.

Pesticide Disposal

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal

Bulk

Thoroughly clean container before reuse. Consult Federal, state, or local disposal authorities for approved alternative procedures.

250 Gal. Mini Bulk

This is a refillable container that must be returned to an authorized Syngenta refilling facility for refilling or disposal. Before refilling, inspect thoroughly for damage such as cracks, punctures, bulges, dents, abrasions, and damaged or worn threads on closure devices. After filling and before transporting, check for leaks. Do not refill or transport damaged or leaking container.

Other Containers

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

CONTAINER IS NOT SAFE FOR FOOD, FEED, OR DRINKING WATER.

Note: For minor spills, leaks, etc. follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during clean up and disposal of wastes.

The Syngenta logo and the CP FRAME  are trademarks of a Syngenta Group Company.

©2009 Syngenta

For non-emergency (e.g. current product information)
call Syngenta Crop Protection, Inc. at 1-800-334-9481

Manufactured for:
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, North Carolina 27419-8300

SCP 1270A-M(draft treenuts)

EmaBenzTech II 1270A-M(draft treenuts)clean-lg-3-5-09 000100-01270.20090305.treenuts.pdf

AM-7

FAST-TRACK AMENDMENTS-Completeness Screening Checklist

Experts In-Processing Signature: _____

EPA Reg. Number: 100 - 1270		EPA Receipt Date: 4/10/09		
	Check List Item	Yes	No	NA
1	Application Form (EPA Form 8570-1) -signed?	X		
2	Confidential Statement of Formula (EPA Form 8570-29) - signed?			X
3	Certification with Respect to Citation of Data (EPA Form 8570-34) signed?			X
4	Formulator's Exemption Statement (EPA Form 8570-27) - signed?			X
5	Data Matrix (EPA Form 8570-35) [Applicable, for adding me-too uses]			
	a) Selective Method?			
	b) Cite-All Method? Applicant owns data or list only the companies offered to pay			
	c) Public copy of Matrix provided? See PR Notice 98-5			
6	Is Label Included? (5 copies)	X		
	Comments: PM-7			

Don -
assigned to you

Receipt for Section 3

S: 348329

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☐ Yes ☒ No

Company: 100 SYNGENTA CROP PROTECTION, INC. V



Risk Manager: Registration Division, Risk Management Team 7

Product #: 100-1270 Product Name: EMAMECTIN BENZOATE TECHNICAL II

Override#:

Me Too Section3: 100-895 Me Too Product Name: AFFIRM TECHNICAL

Application Date: 09-Apr-2009  OPP Rec'd Date: 10-Apr-2009 

Front End Date: 10-Apr-2009  Risk Manager Send Date: 13-Apr-2009 

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

Revision of the label

New Ingredient:

Request Date:

New Ingredient:

Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Paper Label

Electronic Label

View/Edit



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 13, 2009

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

BUNNIE KONAT
SYNGENTA CROP PROTECTION, INC.
ATTN: REGULATORY AFFAIRS
PO Box 18300
GREENSBORO, NC 27419-8300

PRODUCT NAME: EMAMECTIN BENZOATE TECHNICAL II
COMPANY NAME: SYNGENTA CROP PROTECTION, INC.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 100-1270
EPA RECEIPT DATE: 04/10/09

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 7, at (703) 308-6249.

Sincerely,

P. K. Moore

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Fee for Service

gh
{848329H~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr.

7

Receipt No.

S-

848329

EPA File Symbol/Reg. No.

100-1270

Pin-Punch Date:

4/10/2009



This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ ____

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: *RK*

Date: 4-13-09

Remarks:



Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419-8300
Phone: 336 632 6000
www.syngenta.com

Carolyn F. Brinkley
Phone: 336 632 2838
E-mail: carolyn.brinkley@syngenta.com
Telefax: 336 632 5688

Courier Delivery

April 8, 2009

Document Processing Desk [APPL]
Registration Division
US Environmental Protection Agency
One Potomac Yard (South Bldg.)
2777 S. Crystal Drive
Arlington, VA

Attention: Mr. Thomas Harris / Insecticide-Rodenticide Branch

SUBJECT: EMAMECTIN BENZOATE TECHNICAL II (EPA REG. NO. 100-1270)

**ADMINISTRATIVE LABEL AMENDMENT:
APPLICATION TO ADD EPA-APPROVED USE /TREE NUTS CROP
GROUP & PISTACHIOS TO LABEL**

**o TOLERANCES ESTABLISHED & USES REGISTERED IN
2009**

Dear Sir or Madam:

Syngenta Crop Protection, Inc. is submitting an application to revise the label for Emamectin Benzoate Technical II, EPA Reg. No. 100-1270. The directions for use on the label for Emamectin Benzoate Technical II indicate that this product may only be formulated into end-use insecticides for use on the crops that are specified on this technical product label. The tree nuts crop group and pistachios have been added to the list of crops on the Emamectin Benzoate Technical II label. Further explanation of this revision follows.

TOLERANCES ALREADY ESTABLISHED, NEW USE REGISTERED

In 2009 the EPA established tolerances for emamectin benzoate in the tree nuts crop group and pistachios and the Agency approved the use of Proclaim® Insecticide, an emamectin benzoate-based end-use product, for use on these crops. Although Syngenta holds EPA registrations for two technical emamectin benzoate products:

- Emamectin Benzoate Technical, EPA Reg. No. 100-902 and
- Emamectin Benzoate Technical II, EPA Reg. No. 100-1270,

only Emamectin Benzoate Technical II is listed on the EPA-approved confidential statement of formula for Proclaim Insecticide as its source of active ingredient. Therefore Syngenta is adding the tree nuts crop group and pistachios only the label for Emamectin Benaozte Technical II.

ENCLOSED DOCUMENTS

The following documents are provided in support of this label amendment.

- 1) EPA Application for Pesticide Registration (Amendment)
- 2) Two pdf copies of each label – one with revisions marked
- 3) Certification of Label Integrity

Syngenta appreciates the EPA's review of this submission. If you have any questions or comments, please contact me at 336-632-2838 or at Carolyn.brinkley@syngenta.com.

Sincerely yours,



Carolyn F. Brinkley
Sr. Regulatory Product Manager
NAFTA Fungicides & Insecticides

Enclosures





United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 100-1270	2. EPA Product Manager Thomas Harris	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Emamectin Benzoate Technical	PM# IRB	
5. Name and Address of Applicant (Include ZIP Code) Syngenta Crop Protection, Inc. P. O. Box 18300 Greensboro, NC 27419 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

- ☒ Amendment - Explain below. ☐ Final printed labels in response to Agency letter dated _____
- ☐ Resubmission in response to Agency letter dated _____ ☐ "Me Too" Application.
- ☐ Notification - Explain below. ☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.).

Syngenta Crop Protection, Inc. is submitting an application to revise the label for Emamectin Benzoate Technical II, EPA Reg. No. 100-1270. The directions for use on the label for Emamectin Benzoate Technical II indicate that this product may only be formulated into end-use insecticides for use on the crops that are specified on this technical product label. The tree nuts crop group and pistachios have been added to the list of crops on the Emamectin Benzoate Technical II label.

Section - III

1. Material This Product Will Be Packaged In:			2. Type of Container
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
*Certification must be submitted	If "Yes" Unit Packaging wgt. per _____ No. per Contain	If "Yes" Unit Packaging wgt. container _____ No. per	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Carolyn F. Brinkley	Title Sr. Regulatory Product Manager NAFTA Fungicides & Insecticides	Telephone No. (Include Area Code) 336/632-2838
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Carolyn F. Brinkley</i>	3. Title Sr. Regulatory Product Manager NAFTA Fungicides & Insecticides	
4. Typed Name Carolyn F. Brinkley	5. Date April 9, 2009	

Version: 9/11/02

PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
100-1270	March 5, 2009	000100-01270.20090305.treenuts.pdf

Carolyn T. Burdick March 5, 2009
Signature Date

Carolyn F. Brinkley
Name (typed)
Sr. Regulatory Product
Manager

Title

E-LABEL Notice

The electronic copy of the label (PDF on a CD) submitted with this application has been removed by the In-processing Team for entry into the Electronic Label Library* (ELL) to make it available to OPP staff.

You should be using this e-label to conduct your label review.

Note: If the e-label is not found in the ELL then it was probably not named correctly and could not be entered into the ELL. However, the file can be retrieved from the CD which is retained by the In-processing Team.

If the e-label is not found in the ELL, contact Tom Harris, RD (308-9423), Willie Abney, AD (308-1689) or Jim Downing, BPPD (308-9071) for further information and assistance.

*** A Lotus Notes database**

Eamectin Benzoate Technical II

An insecticide for formulation into end-use insecticide products intended for non-domestic terrestrial outdoor food use.

Active Ingredient:

Eamectin Benzoate (CAS No. 155569-91-8) 97.0%

Other Ingredients: 3.0%

Total: 100.0%

KEEP OUT OF REACH OF CHILDREN

WARNING/AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use on label.

EPA Reg. No. 100-1270

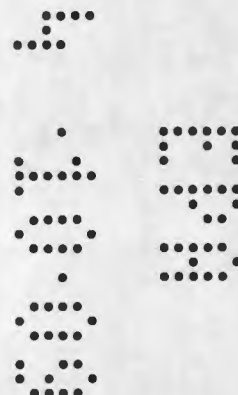
EPA Est. xxxxx

Product of xxxxx

Product ID. xxxx

SCP 1270A-M(draft treenuts)

Net Contents



FIRST AID	
If swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth, if possible. • Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
<p align="center">NOTE TO PHYSICIAN</p> <p>Probably mucosal damage may contraindicate the use of gastric lavage. Early signs of intoxication include dilated pupils, muscular incoordination, and muscle tremors. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements.</p> <p>In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.</p>	
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p>	
<p align="center">HOT LINE NUMBER</p> <p align="center">For 24 Hour Medical Emergency Assistance (Human or Animal) or Chemical Emergency Assistance (Spill, Leak, Fire, or Accident), Call 1-800-888-8372</p>	

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING/AVISO

May be fatal if inhaled or swallowed. Causes moderate eye irritation. Harmful if absorbed through skin. Do not breathe dust. Avoid contact with skin, eyes, or clothing. The following protective clothing must be worn during all handling and formulation operations: airline mask or air supplied hood, chemical-resistant goggles and gloves, full body garments with shoe protectors and head cover. Disposable clothing is recommended. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

Environmental Hazards

This pesticide is toxic to fish, birds, mammals, and aquatic invertebrates. Do not discharge effluent containing this active ingredient into lakes, streams, ponds, estuaries, oceans, or other public waters, unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit, and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.



CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, Inc. or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and, (2) Buyer and User assume the risk of any such use. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.**

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.** ..:::

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.



DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Instructions to Formulators

Formulators using this product are responsible for obtaining Environmental Protection Agency registration for their formulated products.

This technical product may be used only for formulation of end-use insecticides for the uses listed below:

Agricultural crops (Terrestrial Food Crops):

- *Brassica* leafy vegetables crop group 5
- Cotton
- Fruiting vegetables (except cucurbits) crop group 8
- Leafy vegetables (except *Brassica*) crop group 4
- Pome fruit crop group 11
- Tree nuts crop group plus pistachios
- Tobacco
- Turnip greens (tops, leaves)*

*For use on turnip varieties grown for leaves only. Do not use on turnip varieties grown for roots or dual-purpose varieties grown for roots and leaves.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage

Store in a tightly closed original container in a cool, dry place. Do not store near food or feed.

Pesticide Disposal

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal

Bulk

Thoroughly clean container before reuse. Consult Federal, state, or local disposal authorities for approved alternative procedures.

250 Gal. Mini Bulk

This is a refillable container that must be returned to an authorized Syngenta refilling facility for refilling or disposal. Before refilling, inspect thoroughly for damage such as cracks, punctures, bulges, dents, abrasions, and damaged or worn threads on closure devices. After filling and before transporting, check for leaks. Do not refill or transport damaged or leaking container.

Other Containers

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

CONTAINER IS NOT SAFE FOR FOOD, FEED, OR DRINKING WATER.

Note: For minor spills, leaks, etc. follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during clean up and disposal of wastes.

The Syngenta logo and the CP FRAME  are trademarks of a Syngenta Group Company.

| ©20098 Syngenta

For non-emergency (e.g. current product information)
call Syngenta Crop Protection, Inc. at 1-800-334-9481

Manufactured for:
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, North Carolina 27419-8300
| www.syngenta-us.com

| SCP 1270A-M(draft treenuts)

EmaBenzTech II 1270A-M(draft treenuts)marked-Ig-3-5-09



Chron

12-19-07 Approved with comments -1-3-08 revised to EPA comments.

3-5-09-draft- added the tree nuts crop plus pistachios to the list of use sites, removed Syngenta web address

130

130



<carolyn.brinkley@syngenta.com>

09/04/2008 05:57 PM

To Thomas Harris/DC/USEPA/US@EPA

cc <kimberly.clark@syngenta.com>,
<merrill.tisdell@syngenta.com>,
<odette.alexander@syngenta.com>

bcc

Subject Enamectin Benzoate Technical II – Eye Irritation Response

e-file: Enamectin Benzoate Technical II/ App for Regis. & also REI

Dear Tom,

Here is Syngenta's response.

*file 100-1270
no action needed*

syngenta

Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419-8300
Phone: 336 632 6000
www.syngenta.com

Carolyn F. Brinkley
Phone: 336 632 2838
E-E-mail: carolyn.brinkley@syngenta.com
Telefax: 336 632 5688

Delivery via E-mail

September 4, 2008

Mr. Thomas Harris
Registration Division / Insecticide-Rodenticide Branch
Office of Pesticide Programs
US Environmental Protection Agency
One Potomac Yard (South Bldg.)
2777 S. Crystal Drive
Arlington, VA 22202

SUBJECT: EMAMECTIN BENZOATE TECHNICAL II
(epa REG. nO. 100-1270)

RESPONSE TO EPA'S 5/7/08 REVIEW OF 12-HR REI --
reason for DIFFERENT EYE IRRITATION RESULTS FOR EMAMECTIN
BENZOATE technical
(EPA REG. NO. 100-902)

Dear Mr. Harris:

In 2007 the EPA registered Syngenta's new source of technical emamectin benzoate, Emamectin Technical II, EPA Reg. No. 100-1270. Emamectin Benzoate Technical II had slightly higher levels of two impurities and its acute eye irritation and dermal toxicity was different from Emamectin Benzoate Technical, the EPA reviewed the toxicity data for both products and concluded that the two technicals are substantially similar. In a review dated May 7, 2008 EPA did question the difference in eye irritation between the two sources and asked for Syngenta's reply. This letter and the attachment constitute Syngenta's response.

ACUTE EYE IRRITATION STUDY RESULTS FOR EACH SOURCE

An acute eye irritation study Emamectin Benzoate Technical placed eye irritation for this source of technical emamectin benzoate into Category I – Danger. The acute eye irritation study results for Emamectin Benzoate Technical II, however, placed eye irritation for this source of technical emamectin benzoate into Category III – Caution.

ACUTE EYE IRRITATION / RE-ENTRY INTERVAL CHANGE / EPA QUESTIONS

The 40 CFR sets the criteria for determination of the length of time workers must wait to re-enter treated fields (re-entry interval (REI)) without having to wear specified personal protective equipment (PPE). The 40 CFR states that the REI is based upon the results

of the acute dermal toxicity, primary skin irritation, and eye irritation studies. Based upon the Category I eye irritation study results, the EPA determined that end-use products formulated from Emamectin Benzoate Technical, must have a worker re-entry interval of 48 hours. Since the EPA classified the eye irritation study results for Emamectin Benzoate Technical II as Category III, Syngenta proposed that end-use products formulated from this source have an REI of 12 hours. The EPA's Health Effects Division reviewed this proposal (May 7, 2008) and agreed that a 12-hour REI would be appropriate for products produced from this new source of active ingredient. However, the reviewer recommended that Syngenta "describe the reasons (e.g., differences in labs or test methodology) that could account for the difference in acute eye irritation study results (i.e., a major change from Category I to Category III)" for the two sources of technical emamectin benzoate with nearly identical composition.

SYNGENTA'S RESPONSE

A study with the original source of technical emamectin benzoate, Emamectin Benzoate Technical, EPA Reg. No. 100-902 was conducted in 1989 (reported 1992) using six animals. Three animals with severe chemosis were euthanized after 72 hours. One of the three remaining animals was clear of positive effects by 48 hours and the other two by day 8. The three were free of all ocular irritation by day 14. It is unclear how quickly the eyes of the three animals euthanized early would have cleared. There was no corneal opacity, and two had scores of 1 for iris irritation. Had the classification of toxicity been based on the three remaining animals' eye irritation, the study would been classified as Category II, not Category I.

In 2006, Syngenta Crop Protection, Inc. sponsored a primary eye irritation study in rabbits with Emamectin Benzoate Technical II (EPA Reg. 100-1207). In this Guideline study, all three animals were free of positive effects and of all ocular irritation by day 7; the EPA classified eye

irritation for this source of technical emamectin benzoate as Category III. The EPA concluded that the 2006 study with Emamectin Benzoate Technical II is valid and accurate measure of potential eye irritation

Emamectin Benzoate Technical and Emamectin Benzoate Technical II have the same components. The only difference in composition is the level of two impurities is slightly higher in Emamectin Benzoate Technical II. The EPA concluded that this difference did not represent a toxicological concern. However, for two sources of active ingredient with nearly identical composition, the HED considered a change in eye irritation from Category I to Category III a major difference and in the May 2008 review the HED reviewer recommended that Syngenta describe the reason or reasons for the difference. In response, Syngenta reviewed the details of the two studies. A definitive comparison of the results of the two studies is not possible because three animals were euthanized early in the 1989 study with no opportunity for the conjunctival irritation to clear. While minor differences in methodology, animal source, etc., could account for some differences in eye irritation between the two sources of active ingredient, there is no obvious reason in either study for the difference in eye irritation effects. Syngenta concluded that there are no clear reasons for the difference in study results.

ONLY THE NEW SOURCE WILL BE USED TO FORMULATE END-USE PRODUCTS

Since the EPA concluded that products formulated from this source of technical emamectin benzoate qualify for a 12-hour re-entry interval and those formulated from the previous source of emamectin benzoate must have a 48-hour REI, Syngenta decided to base its emamectin-based end-use products solely on the new source of technical emamectin benzoate. Syngenta revised its labels and CSF's for Proclaim® Insecticide, EPA Reg. No.100-904 and Denim® Insecticide, EPA Reg. No.100-903 based upon Emamectin Benzoate Technical II as the only source of active ingredient.

ADDRESSING THE DIFFERENCE IN EYE IRRITATION

The EPA concluded that the eye irritation study with Emamectin Benzoate Technical II is a valid study and classified the effects as Category III. Furthermore, EPA concluded that the appropriate REI for the formulated products is 12 hours. For products with Category III eye irritation, the early entry PPE does not include eye protection. Nonetheless, because nearly identical Emamectin Benzoate Technical is classified as Category I for eye irritation, the EPA required early entry eye protection for workers exposed to products formulated from Emamectin Benzoate Technical II. Syngenta included this language on its labels for Proclaim Insecticide and Denim Insecticide and the company does not object to this additional PPE requirement.

CONCLUSION

A definitive comparison of the results of eye irritation studies with each source of active ingredient is not possible because three animals of six animals were euthanized early in the 1989 Emamectin Benzoate Technical study with no opportunity for the conjunctival irritation to clear. In the 2006 guideline study with Emamectin Benzoate Technical II there was no need to euthanize any animals and all three animals were free of positive effects and free of all ocular irritation by day 7. There are no clear reasons for the difference in eye irritation effects

between Emamectin Benzoate Technical and Emamectin Benzoate Technical II. It is reasonable to speculate, however, that the difference in eye irritation results may have been due to study methodology or animal source.

Although early entry eye protection is not required for Emamectin Benzoate Technical II, a Category III eye irritant, as the Agency required, Syngenta has taken into account the Category I results of the 1989 eye irritation study with Emamectin Benzoate Technical. In addition to the required PPE for early re-entry into areas treated with Proclaim Insecticide or Denim Insecticide, workers are also required to wear eye protection.

If you have any questions or comments about Syngenta's response, please contact me at 336-632-2838 or at carolyn.brinkley@syngenta.com.

Sincerely yours,



Carolyn F. Brinkley
Sr. Regulatory Product Manager /Insecticides

This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.



Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419-8300
www.syngenta.com

February 1, 2008

Document Processing Desk(FPL)
Office of Pesticide Programs (H7504P)
Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

ATTN: Mr. Thomas C. Harris IRB

SUBJECT: Enamectin Benzoate Technical II EPA REG. NO. 100-1270
Submission of Final Printed Version of Labeling in Response to the Conditions of
Registration Required in EPA Approval Letter Dated December 19, 2007.

Dear: Mr. Harris:

Syngenta Crop Protection, Inc. hereby submits 2 copies of final printed version of labeling for Enamectin Benzoate Technical II (EPA Reg. No. 100-1270) as required in EPA approval letter dated December 19, 2007. As per Agency letter, the following label changes have been made:

- a) The EPA Registration Number has been revised to read "EPA Reg. No. 100-1270"
- b) The First Aid section has been reordered to put the most toxic routes of exposure first.
- c) The entire first paragraph of the Precautionary Statements has been replaced with language which reflects the language required in the Agency approval letter.
- d) The Warranty Statement has been revised to reflect language approved by the Office of General Council of the EPA and the legal department of Syngenta.
- e) In the Directions for Use section, the crop group has been revised to read "Leafy Vegetables (except *Brassica*) crop group 4."

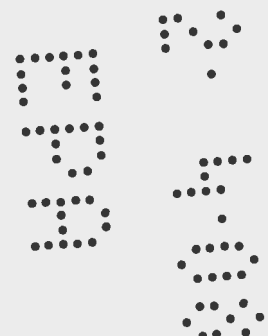
The label copy code is SCP 1270A-L1 1207

We trust that you will find this submission in order; however, should you have any questions, please contact me at 336.632-2838.

Sincerely,

Sr. Regulatory Product Manager/NAFTA Insecticides
Regulatory Affairs

Enclosures: 2 copies of final printed labeling
EPA form 8570-1





United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 100-1270	2. EPA Product Manager Thomas C. Harris	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Emamectin Benzoate Technical II	PM# IRB	
5. Name and Address of Applicant (Include ZIP Code) Syngenta Crop Protection, Inc. P. O. Box 18300 Greensboro, NC 27419 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated December 19, 2007
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

1. **Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)
Syngenta Crop Protection, Inc. hereby submits 2 copies of final printed version of labeling for Emamectin Benzoate Technical II (EPA Reg. No. 100-1270) as required in EPA approval letter dated December 19, 2007. As per Agency letter, the following label changes have been made: a) The EPA Registration Number has been revised to read "EPA Reg. No. 100-1270" b) The First Aid section has been reordered to put the most toxic routes of exposure first. c) The entire first paragraph of the Precautionary Statements has been replaced with language which reflects the language required in the Agency approval letter. d) The Warranty Statement has been revised to reflect language approved by the Office of General Council of the EPA and the legal department of Syngenta. e) In the Directions for Use section, the crop group has been revised to read "Leafy Vegetables (except *Brassica*) crop group 4."
The label copy code is SCP 1270A-L1 1207

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
*Certification must be submitted				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
	If "Yes" Unit Packaging wgt.	No. per Container	If "Yes" Unit Packaging wgt.	No. per container	<input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Carolyn F. Brinkley		Title Sr. Regulatory Product Manager Regulatory Affairs		Telephone No. (Include Area Code) (336) 632- 2838.	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Sr. Regulatory Product Manager Regulatory Affairs			
4. Typed Name Carolyn F. Brinkley		5. Date February 1, 2008			

Emamectin Benzoate Technical II

An insecticide for formulation into end-use insecticide products intended for non-domestic terrestrial outdoor food use.

Active Ingredient:
Emamectin Benzoate (CAS No. 155569-91-8) 97.0%
Other Ingredients 3.0%
Total 100.0%

KEEP OUT OF REACH OF CHILDREN WARNING/AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use on label.

EPA Reg. No. 100-1270 EPA Est. 70992-CHN-001

Product of China

Product ID. **38134**

SCP 1270A-L1 1207

Net Contents

syngenta.

FIRST AID

If swallowed	<ul style="list-style-type: none"> Call a poison control center or doctor immediately for treatment advice. Have person sip glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
If inhaled	<ul style="list-style-type: none"> Move person to fresh air. If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none"> Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN

Probably mucosal damage may contraindicate the use of gastric lavage. Early signs of intoxication include dilated pupils, muscular incoordination, and muscle tremors. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements.

In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

HOT LINE NUMBER

For 24 Hour Medical Emergency Assistance (Human or Animal) or Chemical Emergency Assistance (Spill, Leak, Fire, or Accident), Call
1-800-888-8372

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING/AVISO

May be fatal if inhaled or swallowed. Causes moderate eye irritation. Harmful if absorbed through skin. Do not breathe dust. Avoid contact with skin, eyes, or clothing. The following protective clothing must be worn during all handling and formulation operations: airline mask or air supplied hood, chemical-resistant goggles and gloves, full body garments with shoe protectors and head cover. Disposable clothing is recommended. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

Environmental Hazards

This pesticide is toxic to fish, birds, mammals, and aquatic invertebrates. Do not discharge effluent containing this active ingredient into lakes, streams, ponds, estuaries, oceans, or other public waters, unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit, and the permitting authority has been notified in writing prior to

discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, presence of other materials, weather or crop conditions, or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, Inc. or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions, or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and (2) Buyer and User assume the risk of any such use. TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Instructions to Formulators: Formulators using this product are responsible for obtaining Environmental Protection Agency registration for their formulated products.

This technical product may be used only for formulation of end-use insecticides for the uses listed below:

Agricultural crops (Terrestrial Food Crops):

- Brassica leafy vegetables crop group 5
- Cotton
- Fruiting vegetables (except cucurbits) crop group 8
- Leafy vegetables (except brassica) crop group 4
- Pome fruit crop group 11
- Tobacco
- Turnip greens (tops, leaves)*

*For use on turnip varieties grown for leaves only. Do not use on turnip varieties grown for roots or dual-purpose varieties grown for roots and leaves.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage: Store in a tightly closed original container in a cool, dry place. Do not store near food or feed.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal

Bulk: Thoroughly clean container before reuse. Consult Federal, state, or local disposal authorities for approved alternative procedures.

250 Gal. Mini Bulk: This is a refillable container that must be returned to an authorized Syngenta refilling facility for refilling or disposal. Before refilling, inspect thoroughly for damage such as cracks, punctures, bulges, dents, abrasions, and damaged or worn threads on closure devices. After filling and before transporting, check for leaks. Do not refill or transport damaged or leaking container.

Other Containers: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

CONTAINER IS NOT SAFE FOR FOOD, FEED, OR DRINKING WATER.

Note: For minor spills, leaks, etc. follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during clean up and disposal of wastes.

The Syngenta logo and the Syngenta Group Company.

CP FRAME are trademarks of

©2008 Syngenta

For non-emergency (e.g. current product information) call Syngenta Crop Protection, Inc. at 1-800-334-9481

Manufactured for:
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, North Carolina 27419-8300
www.syngenta-us.com

SCP 1270A-L1 1207



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

EPA Registration
Number:

100-1270

Date of Issuance:

December 19,
2007

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance: **conditional**

Name of Pesticide Product:

Emamectin Benzoate
Technical II

Name and Address of Registrant (include ZIP Code):

Carolyn F. Brinkley
Syngenta Crop Protection, Inc.
PO Box 18300
Greensboro, NC 27419

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) and (B) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Make the following label changes before you release the product for shipment:
 - a. Revise the EPA Registration Number to read, "EPA Reg. No. 100-1270."
 - b. In the First Aid section, reorder the statements to put the most toxic routes of exposure first, i.e. "if swallowed", "if inhaled", "if in eyes", and "if on skin or clothing."
 - c. Replace the entire first paragraph in the Precautionary Statements with the following:

"May be fatal if inhaled or swallowed. Causes moderate eye irritation. Harmful if absorbed through skin. Do not breathe dust. Avoid contact with skin, eyes, or clothing. The following protective clothing must be worn during all handling and formulation operations: Airline mask or air supplied hood, chemical-resistant goggles and gloves, full body garments with shoe protectors and head cover. Disposable clothing is recommended. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco."

(continued on next page)

Signature of Approving Official:

Thomas C. Harris
Biologist
Insecticide Rodenticide Branch
Registration Division (7505P)

Date:

December 19, 2007

(continued)

- d. Change portions of the current similar Warranty text to add "must" and "to the extent consistent with applicable law" so sentences read as follows:

"The Directions for Use of this product must be followed carefully. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

.... To the extent permitted by applicable law, (1) this warranty does not extend to the use of the product contrary to label instructions, or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and, (2) Buyer and User assume the risk of any such use. TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, "

- e. Change "5" to "4" so crop group in Directions for Use reads:

"Leafy vegetables (except *Brassica*) crop group 4"

3. Submit studies to support the following data gaps. Observations must be made at 0, 3, 6, 9, and 12 month intervals. Please submit results in both paper and electronic formats.
- a. one year storage stability (830.6317) - due within 18 months
 - b. corrosion characteristics (830.6320) - due within 18 months
4. Submit two copies of the revised final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label stamped "accepted with comments" is enclosed for your records.

Eamectin Benzoate Technical II

An insecticide for formulation into end-use insecticide products intended for non-domestic terrestrial outdoor food use.

Active Ingredient:

Eamectin Benzoate (CAS No. 155569-91-8) 97.0%

Other Ingredients: 3.0%

Total: 100.0%

KEEP OUT OF REACH OF CHILDREN

WARNING/AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use on label.

EPA Reg. No. 100-xxxx

EPA Est. xxxxx

Product of China

Product ID.

SCP xxxxA(draft-China)

Net Contents

ACCEPTED
with COMENTS
in EPA Letter Dated:
12/19/2007
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
As amended, for the pesticide
Registered under EPA Reg. No.
100-1270

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth, if possible. • Call a poison control center or doctor for treatment advice.
<p align="center">NOTE TO PHYSICIAN</p> <p>Probably mucosal damage may contraindicate the use of gastric lavage. Early signs of intoxication include dilated pupils, muscular incoordination, and muscle tremors. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements.</p> <p>In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.</p>	
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p>	
<p align="center">HOT LINE NUMBER</p> <p align="center">For 24 Hour Medical Emergency Assistance (Human or Animal) or Chemical Emergency Assistance (Spill, Leak, Fire, or Accident), Call 1-800-888-8372</p>	

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals**WARNING/AVISO**

Causes substantial, but temporary, eye injury. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Harmful if swallowed, absorbed through the skin or inhaled. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

Environmental Hazards

This pesticide is toxic to fish, birds, mammals, and aquatic invertebrates. Do not discharge effluent containing this active ingredient into lakes, streams, ponds, estuaries, oceans, or other public waters, unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit, and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product should be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Buyer is solely responsible for any risk created by the use or uses to with it or a User puts this product. SYNGENTA CROP PROTECTION, INC. shall not be responsible for any risk caused by the incorporation of this product into an end-use product by Buyer or User. All such risk shall be assumed by Buyer and user, and Buyer and User agree to hold SYNGENTA and Seller harmless fro any claims relating to such factors. SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use when used in accordance with directions under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and Buyer and User assume the risk of any such use. SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

IT IS SYNGENTA'S AND SELLER'S INTENTION THAT to the extent allowable by State law, SYNGENTA or the Seller shall not be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and of Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Instructions to Formulators

Formulators using this product are responsible for obtaining Environmental Protection Agency registration for their formulated products.

This technical product may be used only for formulation of end-use insecticides for the uses listed below:

Agricultural crops (Terrestrial Food Crops):

- *Brassica* leafy vegetables crop group 5
- Cotton
- Fruiting vegetables (except cucurbits) crop group 8
- Leafy vegetables (except *Brassica*) crop group 5
- Pome fruit crop group 11
- Tobacco
- Turnip greens (tops, leaves)*

*For use on turnip varieties grown for leaves only. Do not use on turnip varieties grown for roots or dual-purpose varieties grown for roots and leaves.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage

Store in a tightly closed original container in a cool, dry place. Do not store near food or feed.

Pesticide Disposal

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal

Bulk

Thoroughly clean container before reuse. Consult Federal, state, or local disposal authorities for approved alternative procedures.

250 Gal. Mini Bulk

This is a refillable container that must be returned to an authorized Syngenta refilling facility for refilling or disposal. Before refilling, inspect thoroughly for damage such as cracks, punctures,

bulges, dents, abrasions, and damaged or worn threads on closure devices. After filling and before transporting, check for leaks. Do not refill or transport damaged or leaking container.

Other Containers

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

CONTAINER IS NOT SAFE FOR FOOD, FEED, OR DRINKING WATER.

Note: For minor spills, leaks, etc. follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during clean up and disposal of wastes.

The Syngenta logo is a trademark of a Syngenta Group Company.

©2006 Syngenta

<p>For non-emergency (e.g. current product information) call Syngenta Crop Protection, Inc. at 1-800-334-9481</p>

Manufactured for:
Syngenta Crop Protection, Inc.
Greensboro, North Carolina 27409
www.syngenta-us.com

SCP xxxxA(draft-China)

EmaBenzTech(draft-China)-lg-11-30-06 000100-xxxxx.20061130.china.pdf

Chron

November 29, 2006 – created label for initial registration of this product which will be produced in China – matches the uses on the label for Enamectin Benzoate Technical (EPA Reg. No. 100-902), however precautionary statements and signal word differ based on results of acute tox texts.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

12/19/2007

Carolyn Brinkley
Syngenta Crop Protection, Inc.
PO Box 18300
Greensboro, NC 27419

Subject: Eramectin Benzoate Technical II, EPA Reg. # 100-1270
reviews associated with initial registration

Dear Ms. Brinkley:

Enclosed please find a copy of the following reviews associated with the initial registration of the above product:

product chemistry - IGairola, RD/TRB, 8/9/2007
acute toxicology - BBackus, RD/TRB, 8/14/2007
similarity - GBurke, HED/TB, 9/27/2007

The acute toxicology profile for this product is:

Acute oral toxicity	II	Acceptable	MRID 47002104
Acute dermal toxicity	III	Acceptable	MRID 47002106
Acute inhalation toxicity	II ^a	Acceptable	MRID 47002107
Primary eye irritation	III	Acceptable	MRID 47002108
Primary dermal irritation	IV ^b	Acceptable	MRID 47002109
Dermal sensitization	Negative	Supplementary	MRID 47002110

^a The registrant has indicated (p. 10 of MRID 47002112, p. 10 of MRID 47002107) that this technical has an LC50 value of 0.663 mg/L in female rats. However, 3/5F died after exposure to 0.506 mg/L and 0/5F died after exposure to 0.239 mg/L. On this basis we would set the LC50 value in females at >0.239 mg/L but <0.506 mg/L, with assignment to Tox. Cat. II.

^b On p. 10 of MRID 47002112 the registrant indicates Tox. Cat. III; however, with a PDII of 0.5 and all scores zero at 72 hours we have assigned it to Tox. Cat. IV.

Sincerely yours,

Thomas C. Harris
Insecticide / Rodenticide Branch
Registration Division (7505C)
Office of Pesticide Programs
harris.thomas@epa.gov
(703) 308-9423

enclosures (3)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460


OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

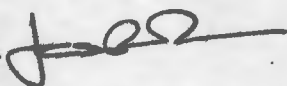
MEMORANDUM

September 27, 2007
TXR # 0054479

SUBJECT: Name of Pesticide Product: Enamectin Benzoate Technical II (Nantong)
EPA Reg. No. /File Symbol: 100-RETN
PC Code: 122806 [Enamectin benzoate 97%]
DP Barcode: D335161

FROM: Gerome Burke, Ph.D. 
Toxicology Branch
Health Effects Division (7509P)

TO: Thomas Harris, Risk Manager
Insecticide Branch
Registration Division (7505P)

THROUGH: Jess Rowland, Ph.D. 
Toxicology Branch
Health Effects Division (7509P)

I. CONCLUSIONS

- Enamectin benzoate technical II (Nantong Crop Protection Co., Ltd) and emamectin benzoate technical (Merck & Co., Inc.) are chemically and toxicologically similar based on chemistry and toxicity characterization.
- Two impurities identified in emamectin benzoate technical II are not of toxicological relevance based on structure and toxicity data collected.

II. ACTION REQUESTED

Review comparative data to register an additional manufacturer of emamectin benzoate technical, Nantong Crop Protection Co., Ltd., Nantong, P.R. China. (MRID 47002101, 47002112)

III. BACKGROUND

Introduction: Syngenta Crop Protection, Inc. has submitted an application to register an additional manufacturer of emamectin benzoate technical (Nantong Crop Protection Co., Ltd., Nantong, P.R. China). The product will be known as emamectin benzoate technical II.

Merck & Co., Inc. produces Emamectin Benzoate Technical for Syngenta Crop Protection, Inc., the registrant for the chemical. Syngenta has concluded, based on chemical analysis and toxicological evaluation, that emamectin benzoate technical II (Nantong Crop Protection Co., Ltd) is equivalent to emamectin benzoate technical.

Citation:

Sparrow, K. (2006). Emamectin Benzoate Technical (MK244) Process Related Impurities Data Supporting Emamectin Benzoate Technical. Syngenta Crop Protection, Inc. Greensboro, NC. Laboratory Project ID: PC-06-138. November 2, 2006. MRID 47002101.

Chukwudebe, A. (2006). Substantial Similarity of Emamectin Benzoate Technical, MK244, to Emamectin Benzoate Technical II. Syngenta Crop Protection, Inc. Greensboro, NC. Laboratory Project ID: T0101782-06. November 29, 2006. MRID 47002112.

Methodology: A comparison of possible toxicities of emamectin benzoate technical (EBT) and emamectin benzoate technical II (EBT II) was performed using selected new acute toxicity studies and/or assessments. Selected studies for emamectin benzoate technical II included: LD₅₀ toxicity (oral, dermal, inhalation), skin and eye irritation, and dermal sensitization. Acute oral and bacterial mutagenicity studies were performed on two major impurities (12-ethyl emamectin B_{1a} benzoate, 24-ethyl emamectin B_{1a} benzoate) found in emamectin benzoate technical II. Product chemistry studies for the two chemicals were also performed.

IV. RESULTS/DISCUSSION

A. Results:

1. Acute LD₅₀ toxicity:

- i. Oral: EBT- 53 mg/kg bw (Category II); EBT II- 208 mg/kg bw (Category II)
- ii. Dermal: EBT- > 2000 mg/kg bw (Category III); EBT II- > 2000 mg/kg bw (Category III)
- iii. Inhalation: EBT- 2.12-4.44 mg/L (Category IV); EBT II- > 1.049 mg/L males/ > 0.663 mg/L females (Category III)

2. Irritation (acute):

- i. Eye: (EBT) Ocular lesions were observed. Ocular reactions persisted up to 14 days. EBT was classified as severely irritating to the eye (Category I). (EBT II) One hour after test dose, positive iritis and conjunctivitis was

observed in three eyes. After 24 hours, positive corneal opacity was observed in two rabbits. Over seven days, the overall severity and incidence decreased until all animals were free of ocular irritation. EBT II was classified as moderately irritating (Category III).

- ii. Skin: (EBT) EBT was classified as non-irritating to the skin (Category IV). (EBT II) All animals were free of dermal irritation within 24 hours. EBT II was classified as slightly irritating to the skin (Category III).

3. Skin sensitization:

- i. EBT and EBT II are not classified as skin sensitizers.

4. Mutagenicity (impurities):

- i. EBT and EBT II are classified as non-mutagenic.

5. Acute Oral (impurities):

- i. The presence of 12-ethyl emamectin B_{1a} benzoate and 24-ethyl emamectin B_{1a} benzoate in EBT II did not affect the toxicity. These impurities are not present in EBT.

6. Product Chemistry:

- i. EBT and EBT II have the same total level of impurities [REDACTED]

B. Discussion:

Emamectin benzoate technical (EBT) and emamectin benzoate technical II (EBT II) have the same total level of impurities [REDACTED]

[REDACTED] The impurities 12-ethyl emamectin B_{1a} benzoate and 24-ethyl emamectin B_{1a} benzoate are not expected to be more toxic than the active isomer. EBT and EBT II have minimal differences with respect to acute toxicities. Also, the Category I LD₅₀ for eye irritation may be due to small differences in methodology. EBT and EBT II are not skin sensitizers or mutagenic.

C. Conclusion:

- Emamectin benzoate technical II (Nantong Crop Protection Co., Ltd) and emamectin benzoate technical (Merck & Co., Inc.) are chemically and toxicologically similar based on chemistry and toxicity characterization.
- Two impurities identified in emamectin benzoate technical II are not of toxicological relevance based on structure and toxicity data collected.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

14 August 2007

MEMORANDUM

Subject: Name of Pesticide Product: EMAMECTIN BENZOATE TECHNICAL II
EPA Reg. No. /File Symbol: 100-RETN
DP Barcode: D335160
Decision No.: 372633
PC Code: 122806 [Emamectin benzoate: 97%]

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
8/14/2007
[Signature]

To: Thomas Harris/John Hebert, RM 07
Insecticide-Rodenticide Branch
Registration Division (7505P)

Registrant: SYNGENTA CROP PROTECTION, INC.

FORMULATION FROM LABEL:

<u>Active Ingredient:</u>	<u>% by wt.</u>
122806 Emamectin benzoate	97%
<u>Other Ingredient(s):</u>	<u>3%</u>
Total:	100%

ACTION REQUESTED: The Risk Manager requests:

"Emamectin technical 100-RETN (similarity claimed to 100-902)... Please review acute product toxicity for new emamectin technical. This is a new source for this technical and is being tracked as a separate product from current source. As per other new 'mectin technicals, this will be sent for review by both RD and HED. RD has lead for reviewing each MRID while HED is asked to comment on claim of similarity especially regarding impurities. Unlike avermectin, there are no other registrants with emamectin technical applications at this time."

BACKGROUND: The material received includes the following MRIDs and acute toxicity studies: 47002104 (acute oral toxicity up-and-down procedure in rats); 47002105 (acute oral toxicity up-and-down procedure in rats); 47002106 (acute dermal toxicity study in rats); 47002107 (4-hour acute inhalation toxicity study in rats); 47002108 (primary eye irritation study in rabbits); 47002109 (primary skin irritation study in rabbits), and 47002110 (skin sensitization LLNA in the mouse). In addition, the material received also includes a document (MRID 47002112) titled: "Substantial Similarity of Emamectin Benzoate Technical, MK 244 (EPA Reg. No. 100-902) to Emamectin Benzoate Technical II," as well as a cover letter (dated December 5, 2006) from the registrant, a proposed label for Emamectin Benzoate Technical II (EPA File Symbol 100-RETN) and an accepted (Feb. 23, 2004) label for EPA Reg. No. 100-902, and CSFs for EPA File Symbol 100-RETN and Reg. No. 100-902.

RECOMMENDATIONS:

1. Five of the acute toxicity studies (MRIDs 47002104, 47002106, 47002107, 47002108, and 47002109) conducted on this technical formulation have been reviewed and classified as acceptable. These studies satisfy the acute oral LD50, dermal LD50, inhalation LC50 and primary eye and dermal irritation toxicity data requirements for the registration of EPA File Symbol 100-RETN. The oral LD50 study for the impurity MRID 47002105 has been classified as supplementary data, as it was terminated following dosage of the fourth rat (too few animals were dosed). The mouse LLNA study in 47002110 has also been classified as supplementary; while there was no evidence for a positive sensitization response, there were only four females per dose group, the positive control group was not concurrent, and the auricular lymph nodes of the 4 mice/group were pooled prior to measurement of the dpm. The OPPTS guidelines for 870.2600 specify a minimum of five animals per dose group, a concurrent positive control, and reporting of individual data (in dpm) from each mouse. The 870.2600 guidelines also include the statement that: "A quantitative assessment must be performed by statistical analysis of individual animal data in order to provide a more complete evaluation of the test substance..."

2. Based on the results of the six acute toxicity studies on the proposed formulation, the following is the tentative acute toxicity profile for EPA File Symbol 100-RETN, EMAMECTIN BENZOATE TECHNICAL II:

Acute oral toxicity	II	Acceptable	MRID 47002104
Acute dermal toxicity	III	Acceptable	MRID 47002106
Acute inhalation toxicity	II ^a	Acceptable	MRID 47002107
Primary eye irritation	III	Acceptable	MRID 47002108
Primary dermal irritation	IV ^b	Acceptable	MRID 47002109
Dermal sensitization	Negative	Supplementary	MRID 47002110

^aThe registrant has indicated (p. 10 of MRID 47002112, p. 10 of MRID 47002107) that this technical has an LC50 value of 0.663 mg/L in female rats. However, 3/5F died after exposure to 0.506 mg/L and 0/5F died after exposure to 0.239 mg/L. On this basis we would set the LC50 value in females at >0.239 mg/L but <0.506 mg/L, with assignment to Tox. Cat. II.

^bOn p. 10 of MRID 47002112 the registrant indicates Tox. Cat. III; however, with a PDII of 0.5 and all scores zero at 72 hours we have assigned it to Tox. Cat. IV.

3. After an evaluation of the material (particularly the acute toxicity profiles) provided by the registrant, it is concluded that it has not been established that 100-RETN and 100-902 are substantially similar. The following is a comparison of their acute toxicity profiles (refer to p. 10 of MRID 47002112):

	100-902	100-RETN
Acute oral toxicity	II	II
Acute dermal toxicity	III	III
Acute inhalation toxicity	IV	II
Primary eye irritation	I	III
Primary dermal irritation	IV	IV
Dermal sensitization	Negative	Negative

4. The major difference of concern between the two technicals appears to be in the acute inhalation toxicity, although it is not evident whether this is from the presence and/or increased amounts of one or more impurities, or whether other factors (particle size?) may be involved. On p. 10 of MRID 47002112 it is indicated that 100-902 has inhalation LC50 values between 2.12 and 4.44 mg/L (toxicity category IV). However, from MRID 47002107 the LC50 value for males was between 1.049 mg/L (0/5M died) and 1.981 mg/L (4/5M died), and, as previously indicated, we would set the LC50 value in females at >0.239 mg/L but <0.506 mg/L, with assignment to Toxicity Category II. These results suggest an approximately 4-fold difference in toxicity between the two technicals by this exposure route.

5. Based on the tentative (the dermal sensitization mouse LLNA study in MRID 47002110 is classified as supplementary) acute oral toxicity profile for 100-RETN, as well as other information in the package received by this reviewer (including the proposed label) the following is its precautionary and first aid labeling, as obtained from the Label Review System:

PRODUCT ID #: 000100-01270

PRODUCT NAME: EMAMECTIN BENZOATE TECHNICAL II

PRECAUTIONARY STATEMENTS

SIGNAL WORD: WARNING

Hazards to Humans and Domestic Animals:

May be fatal if inhaled. [An appropriate respiratory device is recommended]. May be fatal if swallowed. Harmful if absorbed through skin. Causes moderate eye irritation. Do not breathe dust. Remove and wash contaminated clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Avoid contact with skin, eyes or clothing. [Wear protective eyewear.]* Wear: Long-sleeved shirt and long pants, Socks, Shoes, and gloves.

*[Protective eyewear may be specified, if appropriate].

First Aid:

If inhaled:

- Move the person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN: Note to PM/CRM/Registrant: The proposed label should contain a "Note to Physician". The following statements are suggested types of information that may be included, if applicable: - technical information on symptomatology; - use of supportive treatments to maintain life functions; - medicine that will counteract the specific physiological effects of the pesticide; - company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

6. For the purposes of registration, the CSF dated August 21, 2006 for the proposed product may also have to be reviewed and accepted by the TRB Chemistry Team.

Reviewer: Byron T. Backus, Ph.D.
Risk Manager: 07

Date: August 6, 2007

STUDY TYPE: Acute Oral Toxicity (Up-and-Down Method) - Rat; OPPTS 870.1100; OECD 425

TEST MATERIAL: Eamectin Technical, Batch ID SNA6B019; a white powder with a purity (content of MK244) of 96.2%. "At the request of the sponsor, the sample was administered as a 6% w/v suspension in a 0.5% w/w solution of carboxymethylcellulose (CMC) in distilled water (60 mg/mL)..."

CITATION: Durando, J. (2006). Eamectin Technical (MK244G): Acute Oral Toxicity Study in Rats. Eurofins | Product Safety Laboratories, Dayton, NJ 08810. PSL Study No. 19852; Syngenta No. T010796-05. Study completion date: August 1, 2006. MRID 47002104. 17 p. Unpublished.

SPONSOR AND SUBMITTER: SYNGENTA CROP PROTECTION

EXECUTIVE SUMMARY: In an acute oral toxicity up-and-down method study (MRID 47002104), Eamectin Technical, Batch ID SNA6B019, a white powder with a purity of 96.2%, as a 6% w/v suspension in a 0.5% w/w solution of carboxymethylcellulose in distilled water, was administered to a total of 7 fasted (overnight) young (9-11 weeks) adult female Sprague-Dawley derived albino rats (body weights: 168-225 g; source: Ace Animals, Inc., Boyertown, PA). The initial test subject received a dose of 23.7 mg/kg (based on an estimated LD₅₀ value of 75 mg/kg supplied by the study sponsor); subsequent dosages were 75 mg/kg (2 rats), 237 mg/kg (3 rats) and 750 mg/kg (1 rat).

There was no mortality (or signs of toxicity) at doses of up to and including 75 mg/kg; two of 3 rats dosed at 237 mg/kg were found dead, one on day 1 and the other on day 5, while one rat dosed at this level survived. Signs of toxicity at 237 mg/kg included hypoactivity, soft feces, diarrhea, ano-genital staining, tremors, facial staining, and reduced fecal volume. The one survivor had recovered on day 10. The one rat dosed at 750 mg/kg died on day 1; signs of toxicity included hypoactivity, diarrhea and ano-genital staining. All rats dosed at 23.7 and 75 mg/kg gained weight in the period from day 0 to 7 and again from day 7 to 14; the one surviving rat at 237 mg/kg lost 7 g between day 0 and 7 but gained 39 g between day 7 and 14.

Gross necropsy of the rats which died after dosage at 237 or 750 mg/kg showed red intestines; rats which survived the 14-day observation period showed no gross abnormalities.

Estimated Oral LD₅₀ (female rat) = 237 mg/kg with an approximate 95% PL [Profile-likelihood based confidence interval] of 69.53-755 mg/kg. The statement is made on p. 14 of the report that: "The acute oral LD₅₀ of Eamectin Technical expressed as base compound is 208 mg/kg body weight in female rats." Since the molecular weight of Eamectin B_{1a} Benzoate (C₅₆H₈₁NO₁₅) is approximately 1007, then the base part (without the benzoic acid) would have a MW of 885; $885/1007 = 0.87885$; and $237 \times 0.87885 = 208$.

Toxicity based on the oral LD₅₀ value: EPA Toxicity Category II.

This acute oral study is classified as Acceptable. It does satisfy the guideline requirement for an acute oral study (OPPTS 870.1100; OECD 425) in the rat.

COMPLIANCE: Signed and dated GLP Compliance (p. 3 & 5), Quality Assurance (p. 6), and [No] Data Confidentiality (p. 2) statements were provided.

RESULTS and DISCUSSION:

The test material was administered as a 6% w/v suspension in a 0.5% w/w solution of carboxymethylcellulose in distilled water.

AOT425statpgm (Version: 1.0) Test Results and Recommendations
Acute Oral Toxicity (OECD Test Guideline 425) Statistical Program

Date/Time: Monday, August 06, 2007, 2:56:43 PM

Data file name: emamectin.dat

Last modified: 8/6/2007 2:56:40 PM

Test/Substance: emamectin technical

Test type: Main Test

Limit dose (mg/kg): 2000

Assumed LD50 (mg/kg): 75

Assumed sigma (mg/kg): 0.5

Recommended dose progression: 2000, 750, 237, 75, 23.7, 7.5, 2.37, 0.75

DATA:

Test Seq.	Animal ID	Dose (mg/kg)	Short-term Result	Long-term Result
-----------	-----------	--------------	-------------------	------------------

1	3101	23.7	O	O
2	3102	75	O	O
3	3103	237	X	X
4	3104	75	O	O
5	3105	237	O	O
6	3106	750	X	X
7	3107	237	X	X

(X = Died, O = Survived)

Dose Recommendation: The main test is complete.

Stopping criteria met: LR criterion.

SUMMARY OF LONG-TERM RESULTS:

Dose	O	X	Total
23.7	1	0	1
75	2	0	2
237	1	2	3
750	0	1	1
All Doses	4	3	7

Statistical Estimate based on long term outcomes:

Estimated LD50 = 237 (The one dose with partial response).
95% PL Confidence interval is 69.53 to 755.

A. Mortality – There was no mortality at doses of up to and including 75 mg/kg; two of 3 rats dosed at 237 mg/kg were found dead, one on day 1 and the other on day 5, while one rat dosed at this level survived. The one rat dosed at 750 mg/kg died on day 1.

B. Clinical Observations – There were no signs of toxicity at doses of up to and including 75 mg/kg. Signs of toxicity at 237 mg/kg included hypoactivity, soft feces, diarrhea, ano-genital staining, tremors, facial staining, and reduced fecal volume. One rat died on day 1, the other on day 5; the one survivor had recovered on day 10. The one rat dosed at 750 mg/kg died on day 1; signs of toxicity included hypoactivity, diarrhea and ano-genital staining. All rats dosed at 23.7 and 75 mg/kg gained weight in the period from day 0 to 7 and again from day 7 to 14; the one surviving rat at 237 mg/kg lost 7 g between day 0 and 7 but gained 39 g between day 7 and 14.

C. Gross Necropsy - Gross necropsy of the rats which died after dosage at 237 or 750 mg/kg showed red intestines; rats which survived the 14-day observation period showed no gross abnormalities.

D. Reviewer's Conclusions: The rat oral LD₅₀ (female) in this study is 237 mg/kg. This defines an EPA Toxicity Category II hazard potential for this technical formulation by the oral exposure route.

Reviewer: Byron T. Backus, Ph.D.
Risk Manager: 07

Date: August 7, 2007

STUDY TYPE: Acute Oral Toxicity (Up-and-Down Method) - Rat; OPPTS 870.1100; OECD 425

TEST MATERIAL: SYN545012, Batch no. BPS 1215/1; an extremely pale yellow powder, containing $88 \pm 5\%$ of the active SYN 545012. SYN 545012 is described as the sum of SYN 545010 and SYN 545011 (12-Ethyl emamectin benzoate B1a and 24-Ethyl emamectin benzoate B1a).

CITATION: Pooles, A. (2006). Emamectin: SYN545012: Acute Oral Toxicity in the Rat – Up and Down Procedure. Safepharm Laboratories Ltd., Derbyshire, UK. Report No. SPL 0006/0680; Syngenta No. T011271-06. Study completion date: February 28, 2006. MRID 47002105. 20 p. Unpublished.

SPONSOR AND SUBMITTER: SYNGENTA CROP PROTECTION

EXECUTIVE SUMMARY: In an acute oral toxicity up-and-down method study (MRID 47002105), SYN545012, Batch No. BPS 1215/1; an extremely pale yellow powder containing $88 \pm 5\%$ SYN 545012, was orally administered to a total of 4 female Sprague-Dawley CD (CrI: CD® (SD) IGS BR) rats at doses of 55 mg/kg (1 rat), 175 mg/kg (2 rats) and 550 mg/kg (1 rat). The test material was administered as a solution in distilled water with a dosage volume of 10 mL/kg. At the request of the sponsor the study was terminated due to a shortage of test material after the fourth animal had been dosed. An estimated LD50 value was calculated from the limited results.

There was no mortality (or signs of toxicity) in the one rat dosed at 55 mg/kg. At 175 mg/kg both rats survived, but both had signs of toxicity, which included hunched posture, lethargy, ataxia, occasional body tremors, tiptoe gait and piloerection. One rat was completely recovered on day 11, while the other was completely recovered on day 14. At 550 mg/kg the one rat was killed in extremis on day 4; with signs of toxicity generally similar to those seen at 175 mg/kg, but also including (on day 4) diuresis and dehydration. The rat dosed at 55 mg/kg had bodyweight gains from day 0 to 7 (33 g) and day 7 to 14 (17 g). One of the rats dosed at 175 mg/kg had a slight weight loss (3 g) between day 0 and 7, and then had a weight gain of 21 g between day 7 and 14. The other rat dosed at 175 mg/kg gained 18 g between day 0 and 7 and 8 g from day 7 to 14. The rat dosed at 550 mg/kg weighed 233 g on day 0 and 206 g at death (weight loss of 27 g).

No abnormalities were observed at gross necropsy, either in the survivors or in the rat which was euthanized.

Estimated Oral LD₅₀ (female rat) > 175 mg/kg (based on the available data).

Toxicity based on the oral LD₅₀ value: EPA Toxicity Category II.

This acute oral study is classified as Supplementary as too few rats were dosed. It does not satisfy the guideline requirement for an acute oral study (OPPTS 870.1100; OECD 425) in the rat.

COMPLIANCE: Signed and dated GLP Compliance (p. 3), Quality Assurance (p. 5), and [No] Data Confidentiality (p. 2) statements were provided.

RESULTS and DISCUSSION:

The test material was administered as a solution in distilled water with a dosage volume of 10 mL/kg.

AOT425statpgm (Version: 1.0) Test Results and Recommendations
Acute Oral Toxicity (OECD Test Guideline 425) Statistical Program

Date/Time: Tuesday, August 07, 2007, 2:02:55 PM

Data file name: SYN545012.dat

Last modified: 8/7/2007 2:02:52 PM

Test/Substance: SYN545012

Test type: Main Test

Limit dose (mg/kg): 2000

Assumed LD50 (mg/kg): 175

Assumed sigma (mg/kg): 0.5

Recommended dose progression: 2000, 550, 175, 55, 17.5, 5.5, 1.75

DATA:

Test Seq.	Animal ID	Dose (mg/kg)	Short-term Result	Long-term Result
-----------	-----------	--------------	-------------------	------------------

1	1	55	O	O
2	2	175	O	O
3	3	550	X	X
4	4	175	O	O

(X = Died, O = Survived)

Dose Recommendation: Dose the next animal at 550 mg/kg.

SUMMARY OF LONG-TERM RESULTS:

Dose	O	X	Total
55	1	0	1
175	2	0	2
550	0	1	1
All Doses	3	1	4

Statistical Estimate based on long term outcomes:

The estimated LD50 and confidence interval(s) are preliminary because no stopping criteria were met.

Estimated LD₅₀ = 486.1 (Based on an assumed sigma of 0.5).
Approximate 95% confidence interval is 175 to 550.

A. Mortality – There was no mortality at doses up to and including 175 mg/kg; the one rat dosed at 550 mg/kg was sacrificed in extremis on day 4.

B. Clinical Observations – There were no signs of toxicity in the one rat dosed at 55 mg/kg. At 175 mg/kg both rats survived, but both had signs of toxicity, which included hunched posture, lethargy, ataxia, occasional body tremors, tiptoe gait and piloerection. One rat had completely recovered on day 11, while the other had completely recovered on day 14. At 550 mg/kg the one rat was killed in extremis on day 4; with signs of toxicity generally similar to those seen at 175 mg/kg, but also including (on day 4) diuresis and dehydration. The rat dosed at 55 mg/kg had bodyweight gains from day 0 to 7 (33 g) and day 7 to 14 (17 g). One of the rats dosed at 175 mg/kg had a slight weight loss (3 g) between day 0 and 7, and then had a weight gain of 21 g between day 7 and 14. The other rat dosed at 175 mg/kg gained 18 g between day 0 and 7 and 8 g from day 7 to 14. The rat dosed at 550 mg/kg weighed 233 g on day 0 and 206 g at death (weight loss of 27 g).

C. Gross Necropsy - No abnormalities were observed at gross necropsy, either in the survivors or in the rat which was euthanized.

D. Reviewer's Conclusions: The rat (female) estimated oral LD₅₀ in this study is 486.1 mg/kg, but given the severity of the symptoms at 175 mg/kg the actual oral LD₅₀ is probably closer to 200 mg/kg. While a value in the range from 200-486 mg/kg would indicate an EPA Toxicity Category II hazard potential for this formulation by the oral exposure route, the number of rats used in this study was too low, and it is classified as supplementary data. In any case, the study in MRID 47002104 which gives a better defined LD₅₀ value of 237 mg/kg, has been classified as acceptable.

Reviewer: Byron T. Backus, Ph.D.
Risk Manager: 07

Date: August 6, 2007

STUDY TYPE: Acute Dermal Toxicity - Rat; OPPTS 870.1200; OECD 402

TEST MATERIAL: Eamectin Technical, Batch ID SNA6B019; a white powder with a purity (content of MK244) of 96.2%.

CITATION: Durando, J. (2006). Eamectin Technical (MK244G): Acute Dermal Toxicity Study in Rats. Eurofins | Product Safety Laboratories, Dayton, NJ 08810. PSL Study No. 19853; Syngenta No. T010797-05. Study completion date: September 11, 2006. MRID 47002106. 20 p. Unpublished.

SPONSOR AND SUBMITTER: SYNGENTA CROP PROTECTION

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 47002106), a group of 5/sex Sprague-Dawley derived young (9-11 weeks) adult albino rats (males: 307-345 g; females: 211-255 g; source: Ace Animals, Inc., Boyertown, PA) was dermally exposed for 24 hours to 2000 mg/kg of test material. An additional group of 5 females (224-236 g) was similarly exposed at 1000 mg/kg. For both dose levels, the test material was mixed with water (75% w/w test material in distilled water) to form a dry paste which was applied to a 2 inch x 3 inch 4-ply gauze pad which in turn was placed on a dose area of about 2 x 3 inches (approximately 10% of the body surface). The pad and entire trunk of each rat were then wrapped with Durapore tape.

After 24 hours the tape and pads were removed and the test sites cleansed to remove and residual test material. The rats were then observed for 14 days.

Dermal LD₅₀ Males >2000 mg/kg bw (0/5 died)
Dermal LD₅₀ Females >2000 mg/kg bw (2/5 died); at 1000 mg/kg 0/5 died
Dermal LD₅₀ Combined >2000 mg/kg bw (2/10 died)

At 1000 mg/kg all survived, but all showed signs of toxicity which included irregular respiration, tremors and/or reduced fecal volume, with recovery by day 11. All lost weight (from 9 to 29 g) in the period from day 0 to 7, but all weighed more than their initial weight by day 14. At 2000 mg/kg two females were euthanized on day 2. Both showed mouth discharge and were in a moribund condition. All the remaining rats at this dose level showed signs of toxicity, which included hypoactivity, tremors and/or ataxia, with recovery from these symptoms by day 12. All survivors lost body weight (males: 7 to 37 g; females: 18 to 27 g) in the period from day 0 to 7, but all gained weight in the period from day 7 to 14, with two female survivors showing slight (5 and 11 g) weight losses from day 0 to 14. There is no indication within the report that any dermal irritation occurred.

At necropsy, the two females sacrificed on day 2 showed extremely red lungs and facial staining (evidence of salivation). Rats which survived the 14-day observation period showed no gross abnormalities.

Based on the dermal LD₅₀ > 2000 mg/kg, this formulation is in EPA Toxicity Category III in terms of dermal toxicity.

This acute dermal study is classified as Acceptable. It does satisfy the guideline requirement for an acute dermal study (OPPTS 870.1200; OECD 402) in the rat.

COMPLIANCE: Signed and dated GLP Compliance (p. 3 & 5), Quality Assurance (p. 6), and [No] Data Confidentiality (p. 2) statements were provided.

RESULTS and DISCUSSION:

Dose (mg/kg bw)	Mortality/Number Tested		
	Males	Females	Combined
1000	-	0/5	0/5
2000	0/5	2/5	2/10

A. **Mortality** – At 2000 mg/kg two females in moribund condition were euthanized on day 2.

B. **Clinical observations** – At 1000 mg/kg all survived, but all showed signs of toxicity which included irregular respiration, tremors and/or reduced fecal volume, with recovery by day 11. All lost weight (from 9 to 29 g) in the period from day 0 to 7, but all weighed more than their initial weight by day 14. At 2000 mg/kg two females with mouth discharge and moribund condition were euthanized on day 2. All the remaining rats at this dose level showed signs of toxicity, which included hypoactivity, tremors and/or ataxia, with recovery from these symptoms by day 12. All survivors lost body weight (males: 7 to 37 g; females: 18 to 27 g) in the period from day 0 to 7, but all gained weight in the period from day 7 to 14, with two female survivors showing slight (5 and 11 g) overall weight losses from day 0 to 14. There is no indication within the report that any dermal irritation occurred.

C. **Gross Necropsy** - At necropsy, the two females sacrificed on day 2 showed extremely red lungs and facial staining (evidence of salivation). Rats which survived the 14-day observation period showed no gross abnormalities.

D. **Reviewer's Conclusions:** Based on the dermal LD₅₀ > 2000 mg/kg, this formulation is in EPA Toxicity Category III in terms of dermal toxicity.

Reviewer: Byron T. Backus, Ph.D.
Risk Manager: 07

Date: August 7, 2007

STUDY TYPE: Acute Inhalation Toxicity - Rat; OPPTS 870.1300; OECD 403

TEST MATERIAL: Emeamectin Benzoate Technical (MK244G), a white powder with 96.2% w/w purity

CITATION: Noakes, J. P. (2006). Emeamectin Benzoate Technical (MK244G): 4 Hour Acute Inhalation Study in the Rat. Central Toxicology Laboratory, Cheshire, UK. Study No. HR2564; Syngenta No. T010799-05. Study completion date: August 29, 2006. MRID 47002107. 121 p. Unpublished.

SPONSOR AND SUBMITTER: SYNGENTA CROP PROTECTION

EXECUTIVE SUMMARY: In an acute inhalation toxicity study (MRID 47002107), groups of 5M and/or 5F HsdRccHanTM: WIST (Wistar-derived) young (reported as 7-9 weeks) adult albino rats (at exposure: males: 199-252 g; females: 138-181 g; source: Harlan UK Ltd, Bicester, Oxon, OX25 1TP UK) received 4-hour nose-only exposure to target concentrations of 2.0 (measured: 1.981) mg/L, 1.0 (measured: 1.049) mg/L, 0.5 (measured: 0.506) mg/L and 0.25 (measured: 0.239) mg/L. The respective MMADs were 2.89, 3.81, 3.70 and 2.72 μ m, and the corresponding GSDs were 1.67, 1.67, 2.65 and 1.89.

At 1.981 mg/L 4/5 males and 5/5 females were found dead or were humanely euthanized. At 1.049 mg/L 0/5 males died (no females were exposed). At 0.506 mg/L 0/5 males and 3/5 females died or were euthanized. At 0.239 mg/L 0/5 females died (no males were exposed). Deaths occurred on days 2 and 3 (exposure was on day 1). Clinical signs during exposure included slight to moderate salivation. Immediately following exposure at 1.981 mg/L signs of toxicity included reduced stability, hunched posture, shaking and piloerection, with additional signs (increased breathing depth, decreased breathing rate) indicating upper respiratory tract irritation. The one male survivor had recovered on day 12. The one male survivor lost weight (24 g) from day 1 to 8 but then gained 26 g between day 8 and 15.

At 1.049 mg/L (only males exposed) 0/5 died; signs of toxicity included decreased activity, reduced response to sound, salivation, reduced righting and reduced splay reflex, and abnormal respiratory noise, with recovery in all rats by day 10. Two males had small (6-10) weight losses between day 1 and 8, but all had weight gains between day 8 and 15.

At 0.506 mg/L signs included activity decrease, salivation, piloerection and abnormal respiratory noise, with recovery in all males and the two female survivors by day 6. All males gained weight from day 1 to 8 and again from day 8 to 15. The two female survivors lost small amounts of weight (5-7 g) between day 1 and 8, but had weight gains of 21 and 24 g from day 8 to 15.

At 0.239 mg/L (only females exposed) signs included salivation, reduced splay reflex and abnormal respiratory noise, with recovery in all females by day 12. All maintained or gained weight between day 1 and 8, and all gained weight between day 8 and 15.

At gross necropsy one male which died following exposure to 1.981 mg/L had stained nares. None of the other rats had findings which could be attributed to exposure to the test material.

LC₅₀ Males > 1.049 mg/L (0/5 died; at 1.981 mg/L 4/5 died)
LC₅₀ Females reported as 0.663 mg/L with 95% C.L. of 0.270 to 2.23 mg/L; however, 3/5 died after exposure to 0.506 mg/L and 0/5 died after exposure to 0.239 mg/L. On this basis we would set the LC₅₀ value in females at >0.239 mg/L but <0.506 mg/L.

Toxicity based on the rat inhalation LC₅₀ in females (> 0.239 but <0.506 mg/L): EPA Toxicity Category II

This acute inhalation study is classified as Acceptable. It does satisfy the guideline requirement for an acute inhalation study (OPPTS 870.1300; OECD 403) in the rat.

COMPLIANCE: Signed and dated GLP compliance (p. 3), Quality Assurance (p. 5), and [No] Data Confidentiality (p. 2) statements were provided.

RESULTS and DISCUSSION:

Nominal Conc. (mg/L)	Gravi-metric Conc. (mg/L)	MMAD μ m	GSD	Mortality/Number Tested		
				Males	Females	Combined
N.R.	0.239	2.72	1.89	-	0/5	-
N.R.	0.506	3.70	2.65	0/5	3/5	3/10
N.R.	1.049	3.81	1.67	0/5	-	-
N.R.	1.981	2.89	1.67	4/5	5/5	9/10

N.R. = Not Reported

Test Atmosphere / Chamber Description:

Exposure Chamber Volume:	27.6 L
Mean Airflow Rate:	25 LPM
Temperature:	21.2-21.6°C
Relative Humidity:	5-10%
Time to 99% Target Concentration:	Not reported

Test atmosphere concentration (gravimetric) – From p. 13 of MRID 47002107: “The particulate concentration of each test atmosphere, close to the animals’ breathing zone, was measured gravimetrically at least eight times during each exposure. This was done by drawing the test atmosphere, at a known flow rate, for a known time, through a 25 mm diameter, polyvinyl chloride (PVC) GLA 5000 filter housed in a Delrin open-faced filter holder... The filter was weighed before and after the sample was taken...”

Particle size determination - From p. 13 of MRID 47002107: "The aerodynamic particle size distribution of each atmosphere was measured, at least twice during the exposure period, using a Marple Cascade Impactor...which aerodynamically separated airborne particles into pre-determined size ranges. The amount of aerosol, by weight, in each size range, was then used to calculate the aerodynamic particle size distribution of the aerosol. Using a spreadsheet, the data were transformed using a log/probit transform and a linear regression derived from the cumulative data. Using this regression line, the mass median aerodynamic diameter (MMAD) and geometric standard deviation (GSD) were calculated..."

A. Mortality - At 1.981 mg/L 4/5 males and 5/5 females were found dead or were humanely euthanized. At 1.049 mg/L 0/5 males died (no females were exposed). At 0.506 mg/L 0/5 males and 3/5 females died or were euthanized. At 0.239 mg/L 0/5 females died (no males were exposed). Deaths occurred on days 2 and 3 (exposure was on day 1).

B. Clinical observations - Clinical signs during exposure included slight to moderate salivation. Immediately following exposure at 1.981 mg/L signs of toxicity included reduced stability, hunched posture, shaking and piloerection, with additional signs (increased breathing depth, decreased breathing rate) indicating upper respiratory tract irritation. The one male survivor had recovered on day 12. The one male survivor lost weight (24 g) from day 1 to 8 but then gained 26 g between day 8 and 15.

At 1.049 mg/L (only males exposed) signs of toxicity included decreased activity, reduced response to sound, salivation, reduced righting and reduced splay reflex, and abnormal respiratory noise, with recovery in all rats by day 10. Two males had small (6-10) weight losses between day 1 and 8, but all had weight gains between day 8 and 15.

At 0.506 mg/L signs included activity decrease, salivation, piloerection and abnormal respiratory noise, with recovery in all males and the two female survivors by day 6. All males gained weight from day 1 to 8 and again from day 8 to 15. The two female survivors lost small amounts of weight (5-7 g) between day 1 and 8, but had weight gains of 21 and 24 g from day 8 to 15.

At 0.239 mg/L (only females exposed) signs included salivation, reduced splay reflex and abnormal respiratory noise, with recovery in all females by day 12. All maintained or gained weight between day 1 and 8, and all gained weight between day 8 and 15.

C. Gross Necropsy - At gross necropsy one male which died following exposure to 1.981 mg/L had stained nares. None of the other rats had findings which could be attributed to exposure to the test material.

D. Reviewer's Conclusions: The study is acceptable. We can accept the reported LC_{50} (>1.049 mg/L) value for males, however, we cannot accept the reported LC_{50} of 0.663 mg/L for females, as 3/5 died following exposure to 0.506 mg/L and 0/5 died following exposure to 0.239 mg/L (and 5/5 died following exposure to 1.981 mg/L). On this basis we would set the LC_{50} value in females at >0.239 mg/L but <0.506 mg/L. Toxicity based on the rat inhalation LC_{50} in females (>0.239 but <0.506 mg/L): EPA Toxicity Category II.

Reviewer: Byron T. Backus, Ph.D.
Risk Manager: 07

Date: August 10, 2007

STUDY TYPE: Primary Eye Irritation - Rabbit; OPPTS 870.2400; OECD 405

TEST MATERIAL: Emeamectin Technical, Batch ID SNA6B019; a white powder with a purity (content of MK244) of 96.2%.

CITATION: Durando, J. (2006). Emeamectin Technical (MK244G): Primary Eye Irritation Study in Rabbits. Eurofins | Product Safety Laboratories, Dayton, NJ 08810. PSL Study No. 19854; Syngenta No. T010802-05. Study completion date: August 2, 2006. MRID 47002108. 19 p. Unpublished.

SPONSOR AND SUBMITTER: SYNGENTA CROP PROTECTION

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 47002108), 0.1 mL (0.06 g) of Emeamectin Technical, Batch ID SNA6B019, a white powder containing 96.2% MK244, was instilled into the conjunctival sac of the right eye of three (2M & 1F) New Zealand white rabbits (age: young adult; body weights: not reported; source: Robinson Services, Inc., Clemmons, NC). Prior to instillation of the test material, two drops of ocular anesthetic were placed into both eyes of each rabbit. Rabbits were scored (Draize) for eye irritation at 1, 24, 48 and 72 hours, and then at 4 and 7 days after instillation. Fluorescein staining was used to assess corneal damage at 24 hours and, if the eye was positive at 24 hours, at subsequent scoring intervals until the eye scored zero for corneal opacity.

Grade 1 corneal opacity was observed in 2/3 rabbit eyes at 24 hours, and was still present in one eye on day 4, with clearing by day 7. All 3 eyes showed iritis at 1 and 24 hours, still present in 2/3 on day 4, but with clearing by day 7. All 3 eyes were positive (score of 2 or more) for redness and/or chemosis at 1 and 24 hours, and 2/3 eyes were positive for redness on day 4, but all scores were zero on day 7.

In this study, exposure to Emeamectin Technical, Batch ID SNA6B019, a white powder containing 96.2% MK244, caused positive irritation effects in 3/3 rabbit eyes on day 1, but all had completely cleared by day 7. This formulation is in EPA Toxicity Category III in terms of eye irritation potential.

This study is classified as Acceptable. It does satisfy the guideline requirement for a primary eye irritation study (OPPTS 870.2400; OECD 405) in the rabbit.

COMPLIANCE: Signed and dated GLP Compliance (p. 3 & 5), Quality Assurance (p. 6), and [No] Data Confidentiality (p. 2) statements were provided.

RESULTS AND DISCUSSION:

Observations	Hours				Days	
	1	24	48	72	4	7
Corneal Opacity	0/3	2/3	1/3	1/3	1/3	0/3
Iritis	3/3	3/3	2/3	2/3	2/3	0/3
Redness*	3/3	3/3	2/3	2/3	2/3	0/3
Chemosis*	1/3	2/3	0/3	0/3	0/3	0/3
Discharge*	3/3	3/3	1/3	1/3	1/3	0/3

*Score of 2 or more required to be considered "positive."

A. Observations – Grade 1 corneal opacity was observed in 2/3 rabbit eyes at 24 hours, and was still present in one eye on day 4, with clearing by day 7. All 3 eyes showed iritis at 1 and 24 hours, still present in 2/3 on day 4, but with clearing by day 7. All 3 eyes were positive (score of 2 or more) for redness and/or chemosis at 1 and 24 hours, and 2/3 eyes were positive for redness on day 4, but all scores were zero on day 7.

B. Reviewer's Conclusions: In this study, Emamectin Technical, Batch ID SNA6B019, a white powder containing 96.2% MK244, caused positive irritation effects in 3/3 rabbit eyes. These effects were still present in 2/3 eyes on day 4, but had cleared by day 7. This formulation is in EPA Toxicity Category III in terms of eye irritation potential.

Reviewer: Byron T. Backus, Ph.D.
Risk Manager: 07

Date: August 13, 2007

STUDY TYPE: Primary Dermal Irritation - Rabbit; OPPTS 870.2500; OECD 404

TEST MATERIAL: Emeamectin Technical, Batch ID SNA6B019; a white powder with a purity (content of MK244) of 96.2%.

CITATION: Durando, J. (2006). Emeamectin Technical (MK244G): Primary Skin Irritation Study in Rabbits. Eurofins | Product Safety Laboratories, Dayton, NJ 08810. PSL Study No. 19855; Syngenta No. T010800-05. Study completion date: August 2, 2006. MRID 47002109. 16 p. Unpublished.

SPONSOR AND SUBMITTER: SYNGENTA CROP PROTECTION

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 470021098), each of 3 (1M & 2F) young adult New Zealand albino rabbits (weights: not reported; source: Robinson Services, Clemmons, NC) was dermally exposed to 0.5 g Emeamectin Technical, Batch ID SNA6B019, a white powder with a purity (MK244 content) of 96.2%. The test material was moistened with distilled water and 0.67 g of the resulting dry paste (a 75% w/w mixture; $0.67 \text{ g} \times 0.75 = 0.5 \text{ g}$) was placed on a 1-inch square 4-ply gauze pad which was applied to an intact 6-cm² dose site on each animal. The pad and entire trunk of each rabbit were wrapped with semi-occlusive Micropore tape and Elizabethan collars were placed on each animal for the duration of the exposure period.

After 4 hours of exposure, the tape and gauze were removed and the test sites were cleansed of any residual test material.

Sites were scored (Draize) for dermal irritation at ½-1, 24, 48 and 72 hours after gauze removal.

At ½-1 hour all 3 sites scored "1" for erythema and zero for edema. At 24 hours 2/3 sites scored "1" for erythema; all other scores were zero. At 48 hours 1/3 sites scored "1" for erythema; all other scores were zero. At 72 hours all scores for both erythema and edema were zero. The Primary Dermal Irritation Index (PDII) = 0.5.

The effects (a PDII of 0.50; maximum scores of "1" for erythema and zero for edema, with all scores zero at 72 hours) are consistent with an assignment of this product to Toxicity Category IV for dermal irritation.

This study is classified as Acceptable. It does satisfy the guideline requirement for a primary dermal irritation study (OPPTS 870.2500; OECD 404) in the rabbit.

COMPLIANCE: Signed and dated GLP Compliance (p. 3), Quality Assurance (p. 5), and [No] Data Confidentiality (p. 2) statements were provided.

RESULTS and DISCUSSION:

INDIVIDUAL SKIN IRRITATION SCORES

ERYTHEMA/EDEMA

Animal No.	Sex	Hours			
		½-1	24	48	72
3501	F	1/0	0/0	0/0	0/0
3502	M	1/0	1/0	1/0	0/0
3503	F	1/0	1/0	0/0	0/0

A. Observations – There were no indications of systemic toxicity.

B. Results - At ½-1 hour all 3 sites scored “1” for erythema and zero for edema. At 24 hours 2/3 sites scored “1” for erythema; all other scores were zero. At 48 hours 1/3 sites scored “1” for erythema; all other scores were zero. At 72 hours all scores for both erythema and edema were zero. The Primary Dermal Irritation Index (PDII) = 0.5.

C. Reviewer’s Conclusions: The dermal effects (a PDII of 0.50; maximum scores of “1” for erythema and zero for edema, with all scores zero at 72 hours) are consistent with an assignment of this product to Toxicity Category IV in terms of dermal irritation.

Reviewer: Byron T. Backus, Ph.D.
Risk Manager: 07

Date: August 13, 2007

STUDY TYPE: Dermal Sensitization – Local Lymph Node Assay in the Mouse; OPPTS 870.2600; OECD 429

TEST MATERIAL: Emeamectin Benzoate Technical (MK244G), batch reference no. SNA6B019; described as a white powder with a purity of 96.20%.

CITATION: Betts, C.J. (2006). Emeamectin Benzoate Technical (MK244G) Skin Sensitisation – Local Lymph Node Assay in the Mouse, Final Report. Central Toxicology Laboratory, Cheshire, UK. Laboratory Report No. GM8013-REG-R1; Task No. T010803-05. Study completion date: July 31, 2006. MRID 47002110. 21 p. Unpublished.

SPONSOR AND SUBMITTER: SYNGENTA CROP PROTECTION

EXECUTIVE SUMMARY: In a dermal sensitization study (MRID 47002110) with Emeamectin Benzoate Technical (MK244G), Batch reference no. SNA6B019, a white powder containing 96.2% active, 4/group young adult female mice (Strain: CBA/Ca/Ola/Hsd, Age: 8-12 weeks; Weight: 14.5-19.5 g; Source: Harlan Interfauna UK Ltd., Oxon, UK) were tested in a Local Lymph Node Assay. The test substance was prepared as 0.5%, 1.0% and 2.5% w/v suspensions or solutions in dimethyl formamide. An additional group of 4 mice was treated with vehicle alone. The dose levels were based on "acute oral toxicity data and data obtained from sighting studies whereby mice were exposed topically to the test substance." The test was performed under OECD guidelines, which differ from those of EPA.

Each mouse received one application (approximately 25 µL/ear) of test substance suspension or vehicle to the dorsal surface of both ears once daily for three consecutive days. Alpha-Hexylcinnamaldehyde (HCA) at w/v concentrations of 5%, 10% and 25% in 4:1 acetone: olive oil was used as in a nonconcurrent positive control assay.

On study day 6, the tail vein of each mouse was injected with ~250 µL of phosphate buffered saline (PBS) containing 20 µCi of ³H-methyl thymidine. The mice were sacrificed approximately 5 hours later by inhalation of halothane followed by cervical dislocation. The draining auricular lymph nodes of each ear were removed and pooled with the nodes of other mice from the same group and disaggregated into a single cell suspension. The cell suspensions were washed 3X by centrifugation with approximately 10 mL PBS. Approximately 3 mL of 5% w/v trichloroacetic acid (TCA) was added, and after overnight precipitation at 4°C, the samples were pelleted by centrifugation and the supernatant was discarded. The cells were then resuspended in approximately 1 mL of TCA.

The pooled (by group) lymph node suspensions were transferred to scintillation vials and 10 mL of scintillation fluid was added prior to counting. The radioactivity was measured and reported as disintegrations per minute (dpm) per lymph node for each group. A stimulation index (SI) was derived for each exposure group by dividing the mean dpm of each exposure group by the mean dpm of the vehicle control group.

The criterion for a positive response was that one or more concentrations of the test substance would elicit a 3-fold or greater increase in isotope incorporation (or stimulation index = SI) relative to the

vehicle control group. In this assay the SI values for the 0.5, 1.0 and 2.5% concentrations of Emamectin Benzoate Technical (MK244G) were 1.3, 1.1 and 2.1, respectively.

In the positive control study, the SI values for the 5, 10 and 25% concentrations of HCA in 4:1 acetone: olive oil were 2.1, 2.4 and 7.2 respectively. The positive control assay was conducted in the period from January 25 to January 31, 2006, while the study with Emamectin Benzoate Technical (MK244G) was conducted from June 21 to June 29, 2006.

In this study, there was no indication that Emamectin Benzoate Technical (MK244G), a white powder containing 96.2% active, is a dermal sensitizer. However, the OPPTS guidelines for 870.2600 specify a minimum of five animals per dose group, a concurrent positive control, and reporting of individual data (in dpm) from each mouse. The 870.2600 guidelines also include the statement that: "A quantitative assessment must be performed by statistical analysis of individual animal data in order to provide a more complete evaluation of the test substance..."

This study is classified as supplementary. It does not satisfy the guideline requirement for a dermal sensitization study (OPPTS 870.2600; OECD 429) in the mouse.

COMPLIANCE: Signed and dated GLP Compliance (p. 3), Quality Assurance (p. 5), and [No] Data Confidentiality (p. 2) statements were provided.

I. MATERIALS and METHODS

1. Vehicle and positive control - The vehicle in this study for the test material was dimethylformamide. The vehicle for the positive control material (HCA) was 4:1 acetone:olive oil.

2. Treatment preparation and administration - Four mice/group received one application (25 μ L/ear) of test substance in dimethyl formamide on the dorsal surface of both ears at concentrations of 0.5, 1.0 and 2.5% Emamectin Benzoate Technical (MK244G). The dose levels were based on "acute oral toxicity data and data obtained from sighting studies whereby mice were exposed topically to the test substance." Alpha-Hexylcinnamaldehyde (HCA) at w/v concentrations of 5%, 10% and 25% in 4:1 acetone: olive oil was used as the nonconcurrent positive control substance.

On study day 6, the tail vein of each mouse was injected with ~250 μ L of phosphate buffered saline (PBS) containing 20 μ Ci of 3 H-methyl thymidine. The mice were sacrificed approximately 5 hours later by inhalation of halothane followed by cervical dislocation. The draining auricular lymph nodes of each ear were removed and pooled with the nodes of other mice from the same group and disaggregated into a single cell suspension. The cell suspensions were washed 3X by centrifugation with approximately 10 mL PBS. Approximately 3 mL of 5% w/v trichloroacetic acid (TCA) was added, and after overnight precipitation at 4°C, the samples were pelleted by centrifugation and the supernatant was discarded. The cells were then resuspended in approximately 1 mL of TCA.

The pooled (by group) lymph node suspensions were transferred to scintillation vials and 10 mL of scintillation fluid was added prior to counting. The radioactivity was measured and reported as disintegrations per minute (dpm) per lymph node for each group. A stimulation index (SI) was derived for each exposure group by dividing the mean dpm of each exposure group by the mean dpm of the vehicle control group.

II. RESULTS and DISCUSSION:

A. Stimulation Indices (group means) -

Sample Description Test or Control Group	Vehicle	Low (0.5%)	Medium (1.0%)	High (2.5%)	Positive Control (25%)
Stimulation Index (SI)	NA	1.3	1.1	2.1	7.2*

*The SI values for the 5 and 10% concentrations of HCA were 2.1 and 2.4, respectively.

Note: no individual data are presented, as the SI values are based on counts from pooled (by group) lymph nodes.

B. Reviewer's Conclusions: In this study, there was no indication that Emamectin Benzoate Technical (MK244G), a white powder containing 92.6% active, is a dermal sensitizer. However, the OPPTS guidelines for 870.2600 specify a minimum of five animals per dose group, a concurrent positive control, and reporting of individual data (in dpm) from each mouse. The 870.2600 guidelines also include the statement that: "A quantitative assessment must be performed by statistical analysis of individual animal data in order to provide a more complete evaluation of the test substance..." The test was performed under OECD guidelines, which differ from those of EPA.

This study is classified as supplementary. It does not satisfy the guideline requirement for a dermal sensitization study (OPPTS 870.2600; OECD 429) in the mouse.

ACUTE TOX ONE-LINERS

1. **DP BARCODE:** D335160
2. **PC CODE:** 122806 [Emamectin benzoate: 96.2%]
3. **CURRENT DATE:** 13 August 2007
4. **TEST MATERIAL:** Emamectin Benzoate Technical, Batch ID SNA6B019; a white powder with a purity (content of MK244) of 96.2%.

Study/Species/Lab Study # /Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity / rat / Eurofins Product Safety Laboratories / PSL Study No. 19852 / 1-AUG-2006	47002104	Up-and-down procedure: test material given as a 6% w/v suspension in 0.5% CMC in water. No deaths at up to and including 75 mg/kg; 2/3 dosed at 237 mg/kg died; one dosed at 750 mg/kg died. Oral LD50 = 237 mg/kg with 95% PL [Profile-Likelihood based Confidence Interval] 69.53-755 mg/kg.	II	A
Acute oral toxicity / rat / Safepharm Laboratories UK / SPL 0006/0680 / 28-FEB-2006	47002105	Up-and-down procedure: test material administered in distilled water at a constant dose volume of 10 mL/kg. Study terminated after 4 th animal was dosed. No mortality at 55 mg/kg (1 rat), 2/2 survived at 175 mg/kg and one at 550 mg/kg was killed in extremis on day 4. Estimated rat LD50 > 175 mg/kg.	II	S
Acute dermal toxicity / rat / Eurofins Product Safety Laboratories / PSL Study No. 19853 / 11-SEP-2006	47002106	At 2000 mg/kg 0/5M & 2/5F rats died after 24-hr dermal exposure. At 1000 mg/kg 0/5F rats died. All showed symptoms; which included hypoactivity and tremors/atrasia. Dermal LD50 > 2000 mg/kg.	III	A
Acute inhalation toxicity / rat / Central Toxicology Laboratory, Cheshire, UK / CTL No. HR2564 / 29- AUG-2006	47002107	Nose-only exposure: at 1.981 mg/L 4/5M & 5/5F died; MMAD=2.89 µm, GSD=1.67. At 1.049 mg/L 0/5 M died; MMAD=3.81µm; GSD = 1.67. At 0.506 mg/L 0/5M & 3/5F died; MMAD=3.70 µm; GSD=2.65. At 0.239 mg/L 0/5F died; MMAD 2.72 µm; GSD=1.89. LC50(M) >1.049 mg/L; <1.981 mg/L; LC50 (F) >0.239 mg/L; <0.506 mg/L.	II	A

Primary eye irritation / rabbit / Eurofins Product Safety Laboratories / PSL Study No. 19854/ 2-AUG-2006	47002108	All 3 with positive irritation effects, and grade 1 corneal opacity in 2/3 rabbits at 24 hrs, but all eyes clear by day 7.	III	A
Primary dermal irritation / rabbit / Eurofins Product Safety Laboratories / PSL Study No. 19855/ 2-AUG-2006	47002109	PDII=0.5 with 1 the max. score for erythema and zero max score for edema. All scores zero at 72 hours.	IV	A
Dermal sensitization / LLNA - mouse / Central Toxicology Laboratory, Cheshire, UK / CTL No. GM8013-REG-R1 / 31-JUL-2006	47002110	Groups of 4F mice treated with vehicle, 0.5%, 1.0% and 2.5% w/v suspensions of test material in dimethyl formamide. Auricular lymph nodes were pooled with nodes from other mice of same group before counting. SI values of 1.3, 1.1 and 2.1 for 0.5%, 1.0% and 2.5% concentrations respectively. Nonconcurrent positive control (HCA at 25%) gave an SI of 7.2. No indications test material a sensitizer, but not conducted according to OPPTS guidelines.	Not a sensitizer	S

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, W = Waived

FEE

DATE: 08/07/07

SUBJECT: Product Chemistry Review of EMAMECTIN BENZOATE TECHNICAL II

FROM: Indira Gairola
Product Chemistry Team
Technical Review Branch/RD (7505P)

SRB 8/9/07

TO: John Herbert /Tom Harris PM 07
Insecticide Rodenticide Branch/RD (7505P)

DP BARCODE No.: 335159

File Symbol No.: 100-RETN

COMPANY: SYNGENTA CROP PROTECTION, INC.

PCC: 122806

Decision No. 372633

Chemical Name: (IUPAC, ANSI, etc.) Emamectin benzoate

CAS No. 155569-91-8

USE: Insecticide

INTRODUCTION:

SYNGENTA has submitted Product Chemistry Guideline reference 830 Subgroup A & B data to support the registration of EMAMECTIN BENZOATE TECHNICAL.

Applicant claims the subject product EMAMECTIN BENZOATE TECHNICAL to be similar to EPA Reg. No.100-902 especially regarding the impurities.

Details are listed below:

SUMMARY OF FINDINGS:

1. Applicant SYNGENTA has submitted MRID#s 470021-01,-02,-03 &-12 for Product Chemistry data to support the registration of EMAMECTIN BENZOATE TECHNICAL.
2. The submitted package was reviewed and details of product chemistry data will be discussed in the following Pages:
3. The Basic Formulation CSF dated 08/21/06 is filled out completely and correctly.
4. The certified limits are in compliance with 40 CFR158 .175 (b) (2).

5. Average recovery of EMAMECTIN BENZOATE TECHNICAL ranged from acceptable level of 96.4%-97.6% Mean Average =97.0%.
6. The subject product EMAMECTIN BENZOATE TECHNICAL is similar to EPA Reg. No.100-902 especially regarding the impurity profile.

CONCLUSIONS:

TRB has reviewed the product chemistry data submitted for the above mentioned subject product and has concluded that:

1. Product Chemistry data requirements for subgroup A are satisfactory and fulfill the requirement of OPP test guidelines.
2. Certified limits are in compliance with 40CFR.175 (b) (2). See CONFIDENTIAL APPENDIX.
3. Average recovery of EMAMECTIN BENZOATE TECHNICAL ranged from acceptable level of 96.4%-97.6% Mean Average =97.0%.
4. The Basic Formulation CSF dated 08/21/06 is acceptable.
5. The subject product EMAMECTIN BENZOATE TECHNICAL is similar to EPA Reg. No.100-902 especially in regards to impurity profile.

Sub Group 'A' Guidelines Series 830.1550-1800
DP BAR CODE: 335159 File Symbol No.: 100-RETN
PRODUCT NAME: EMAMECTIN BENZOATE TECHNICAL

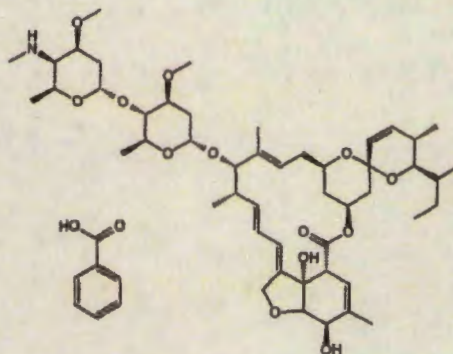
Table 1: Manufacturing and Impurity Data for IMAZAPYR TECHNICAL				
GLN	Requirement	MRID	Status ¹	Details and/or Deficiency ²
830.1550	Product Identity & Disclosure of Ingredients		A	08/21/06
830.1600 830.1620 830.1650	Starting Materials & Manufacturing Process		A	MRID # 470021-02
830.1670	Discussion of Impurities		A	MRID # 470021-02
830.1700	Preliminary Analysis		A	MRID # 470021-02
830.1750	Certification of Limits		A	08/21/06
830.1800	Analytical Methods		A	MRID # 470021-02
¹ A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable. ² Refer to CBI Appendix A for details.				

SUB GROUP A

Product Identity

Chemical Class:	Avermectin
Product Category:	Insecticide
Common Name:	Emamectin Benzoate
Company Code Number:	MK244
Chemical Abstract Number:	155569-91-8
Empirical Formula:	Emamectin Benzoate B _{1a} : C ₄₉ H ₇₅ NO ₁₃ •C ₇ H ₆ O ₂ Emamectin Benzoate B _{1b} : C ₄₈ H ₇₃ NO ₁₃ •C ₇ H ₆ O ₂
Chemical Name:	IUPAC: 4''-Epi-methylamino-4''-deoxyavermectin B ₁ benzoate CAS: Avermectin B ₁ , 4''-deoxy-4''-(methylamino)- (4''R)-, benzoate (salt)
Molecular Weight:	Emamectin Benzoate B _{1a} : 1008.26 Emamectin Benzoate B _{1b} : 994.23

Molecular Structure:



I MANUFACTURING PROCESS (830.1620):

For details please refer to the CONFIDENTIAL APPENDIX.

II DISCUSSION OF FORMATION OF IMPURITIES (830.1670):

This portion will be discussed in CONFIDENTIAL APPENDIX

III PRELIMINARY ANALYSES 830.1700 are discussed in the following pages.

IV CERTIFIED LIMITS

Please refer to the CONFIDENTIAL APPENDIX for CSF.

V. ENFORCEMENT ANALYTICAL METHOD (830.1800)

Is discussed in PreliminaryAnalyses.

1V CERTIFIED LIMITS:

Please refer to the attached CSF



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 11, 2006

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SYNGENTA CROP PROTECTION, INC.
ATTN: REGULATORY AFFAIRS
PO Box 18300
GREENSBORO, NC 27419-8300

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 06-DEC-06. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

**VOLUME 1 OF 13 OF SUBMISSION
(TRANSMITTAL DOCUMENT)**

1. Name and Address of Submitter

Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419

2. Regulatory Action in Support of which this Package is Submitted

Application for New Product Registration
Emamectin Benzoate Technical II, EPA REG. NO. 100-XXXX

3. Transmittal Date

12/5/2006

4. List of Submitted Studies

MRID NUMBER	VOLUME NUMBER	STUDY TITLE	EPA GUIDELINE NUMBER
	1 OF 13	Transmittal document	NA
47002101	2 OF 13	Emamectin Benzoate -Process Related Impurities Data Supporting Emamectin Benzoate Technical;(PC-06-138), (09003aeb80227aaa),(450289)	830.1550, 830.1700
47002102	3 OF 13	Manufacturing Process Description and Supporting Data for Emamectin Technical;(PC-06-074), (09003aeb80227aaa),(445971)	830.1550, 830.1600, 830.1620, 830.1670, 830.1700, 830.1750,
47002103	4 OF 13	Emamectin Benzoate -Physical and Chemical Properties of Emamectin Benzoate Technical II;(PC-06-126), (09003aeb80227aaa),(449799)	830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, 830.6321, 830.7000, 830.7050, 830.7100, 830.7200, 830.7220, 830.7300, 830.7370, 830.7550, 830.7840,

MRID NUMBER	VOLUME NUMBER	STUDY TITLE	EPA GUIDELINE NUMBER
47002104	5 OF 13	Enamectin Technical (MK244G) -Acute Oral Toxicity Up and Down Procedure in Rats;(T010796-05), (09003aeb80227aaa),(448023)	870.1000
47002105	6 OF 13	SYN545012 -Acute Oral Toxicity in the Rat -Up and Down Procedure; (T011271-06),(09003aeb80227aaa), (450659)	870.1100
47002106	7 OF 13	Enamectin Technical (MK244G) -Acute Dermal Toxicity Study in Rats; (T010797-05),(09003aeb80227aaa), (449204)	870.1200
47002107	8 OF 13	Enamectin Benzoate -4 Hour Acute Inhalation Toxicity Study in the Rat; (T010799-05),(09003aeb80227aaa), (449060)	870.1300
47002108	9 OF 13	Enamectin Technical (MK244G) - Primary Eye Irritation Study in Rabbits; (T010802-05),(09003aeb80227aaa), (448026)	870.2400
47002109	10 OF 13	Enamectin Technical -Primary Skin Irritation Study in Rabbits; (T010800-05),(09003aeb80227aaa), (448020)	870.2500
47002110	11 OF 13	Enamectin Benzoate -Skin Sensitisation -Local Lymph Node Assay in the Mouse; (T010803-05),(09003aeb80227aaa), (448019)	870.2600
47002111	12 OF 13	Sum of 12-ethyl and 24-ethyl Enamectin BIa (SYN545012) -Bacterial Mutation Assay in S.typhimurium and E.coli; (T018147-04),(09003aeb80227aaa), (450641)	870.5100

MRID NUMBER	VOLUME NUMBER	STUDY TITLE	EPA GUIDELINE NUMBER
----------------	------------------	----------------	-------------------------

47002112	13 OF 13	Emamectin Benzoate -Substantial Similarity of Emamectin Benzoate Technical,MK244 (EPA Reg.No.100-92) to Emamectin Benzoate Technical II; (T010782-06),(09003aeb80227aaa), (450893)	NA
----------	----------	---	----

Company Official: CAROLYN BRINKLEY
(NAME)

Carolyn F Brinkley
(SIGNATURE)

Company Name: SYNGENTA CROP PROTECTION, INC.

Company Contact: CAROLYN BRINKLEY
(NAME)

(336) 632-2838
(PHONE)

NEW APPLICATIONS

DATE: DEC - 6 2006

FILE NUMBER: 100 - RETN

FEP (OPPIN ENTRY): LV 12/6/2006
(Initial & date)

FILE ROOM: _____
(Initial & date)

SIG: 12/12/06 KC
(Initial & date)

FILE ROOM: JC 12/13/06
(Initial & date)

✓ **ASSIGN TO PM** 7 **(NO DATA)**

 JACKET TO SHELF (DATA)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 8, 2006

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT
Or Pay On-Line at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-372633
EPA File Symbol or Registration Number: 100-RETN
Product Name: ABAMECTIN TECHNICAL II
EPA Receipt Date: 06-Dec-2006
EPA Company Number: 100
Company Name: SYNGENTA CROP PROTECTION, INC.

G. THOMAS GALE, JR.
SYNGENTA CROP PROTECTION, INC.
ATTN: REGULATORY AFFAIRS
PO Box 18300
GREENSBORO, NC 27419-8300

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R33

NEW MANUFACTURING USE PRODUCT;OLD AI;SELECTIVE CITATION;

Please remit payment in the amount of: \$ 15,750 to:

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 360277
Pittsburgh, PA 15251

By Courier:

U.S. EPA Washington Finance Center
Pesticide Registration Service Fee
C/O Mellon Client Service Center
500 Ross Street, Room 670
Box 360277
Pittsburgh, PA 15251-6277
Attn: EPA Module Supervisor
Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

Effective November 1, 2006, fees may be paid on-line via credit card or electronic fund transfer. To submit a payment on-line, visit www.pay.gov. From the pay.gov home page, select "search by form name." From the next page, select "P," then click on "Pesticide Registration Improvement Act. Fee Payment" and complete the form, making certain to use the decision number and registration number on the invoice you receive from the Pesticide Program in the space provided.

You may be eligible for a full or partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how to request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

Please send Registration Service Fee Waiver requests to:

By USPS:

Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

By Courier:

Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall #2
1801 S. Bell St.
Arlington, VA 22202

A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 45 days, the Agency will presume that you no longer want to pursue this action. The Agency will then initiate a process that may result in administrative withdrawal of this action.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 305-6249.

Sincerely,



Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

15
{802261u~

This package includes the following

- ☒ New Registration
- ☐ Amendment

✓ Studies? Fee Waiver?
volpay % Reduction: _____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr.

7

Receipt No.

S-

802261

EPA File Symbol/Reg. No.

100-RETN

Pin-Punch Date:

12/6/2006

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

R33

Granted:

R33

Amount Due: \$

15,750

Parent/Child Decisions:

Reviewer: _____

[Signature]

Date: _____

12/8/06

Remarks:

**VOLUME 1 OF 13 OF SUBMISSION
(TRANSMITTAL DOCUMENT)**

1. Name and Address of Submitter

Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419

2. Regulatory Action in Support of which this Package is Submitted

Application for New Product Registration
Emamectin Benzoate Technical II, EPA REG. NO. 100-XXXX

3. Transmittal Date

12/5/2006

4. List of Submitted Studies

MRID NUMBER	VOLUME NUMBER	STUDY TITLE	EPA GUIDELINE NUMBER
	1 OF 13	Transmittal document	NA
	2 OF 13	Emamectin Benzoate -Process Related Impurities Data Supporting Emamectin Benzoate Technical;(PC-06-138), (09003aeb80227aaa),(450289)	830.1550, 830.1700
	3 OF 13	Manufacturing Process Description and Supporting Data for Emamectin Technical;(PC-06-074), (09003aeb80227aaa),(445971)	830.1550, 830.1600, 830.1620, 830.1670, 830.1700, 830.1750,
	4 OF 13	Emamectin Benzoate -Physical and Chemical Properties of Emamectin Benzoate Technical II;(PC-06-126), (09003aeb80227aaa),(449799)	830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, 830.6321, 830.7000, 830.7050, 830.7100, 830.7200, 830.7220, 830.7300, 830.7370, 830.7550, 830.7840,

MRID NUMBER	VOLUME NUMBER	STUDY TITLE	EPA GUIDELINE NUMBER
----------------	------------------	----------------	-------------------------

5 OF 13	Emamectin Technical (MK244G) -Acute Oral Toxicity Up and Down Procedure in Rats;(T010796-05), (09003aeb80227aaa),(448023)	870.1000
6 OF 13	SYN545012 -Acute Oral Toxicity in the Rat -Up and Down Procedure; (T011271-06),(09003aeb80227aaa), (450659)	870.1100
7 OF 13	Emamectin Technical (MK244G) -Acute Dermal Toxicity Study in Rats; (T010797-05),(09003aeb80227aaa), (449204)	870.1200
8 OF 13	Emamectin Benzoate -4 Hour Acute Inhalation Toxicity Study in the Rat; (T010799-05),(09003aeb80227aaa), (449060)	870.1300
9 OF 13	Emamectin Technical (MK244G) - Primary Eye Irritation Study in Rabbits; (T010802-05),(09003aeb80227aaa), (448026)	870.2400
10 OF 13	Emamectin Technical -Primary Skin Irritation Study in Rabbits; (T010800-05),(09003aeb80227aaa), (448020)	870.2500
11 OF 13	Emamectin Benzoate -Skin Sensitisation -Local Lymph Node Assay in the Mouse; (T010803-05),(09003aeb80227aaa), (448019)	870.2600
12 OF 13	Sum of 12-ethyl and 24-ethyl Emamectin B1a (SYN545012) -Bacterial Mutation Assay in S.typhimurium and E.coli; (T018147-04),(09003aeb80227aaa), (450641)	870.5100

MRID NUMBER	VOLUME NUMBER	STUDY TITLE	EPA GUIDELINE NUMBER
----------------	------------------	----------------	-------------------------

13 OF 13

Emamectin Benzoate -Substantial
Similarity of Emamectin Benzoate
Technical,MK244 (EPA Reg.No.100-92)
to Emamectin Benzoate Technical II;
(T010782-06),(09003aeb80227aaa),
(450893)

NA

Company Official: CAROLYN BRINKLEY
(NAME)

Carolyn F Brinkley
(SIGNATURE)

Company Name: SYNGENTA CROP PROTECTION, INC.

Company Contact: CAROLYN BRINKLEY
(NAME)

(336) 632-2838
(PHONE)



United States
Environmental Protection Agency
 Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 100-RETN	2. EPA Product Manager Mr. Thomas Harris	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Emamectin Benzoate Technical II	PM# Insecticide-Rodenticide Branch	
5. Name and Address of Applicant (Include ZIP Code) Syngenta Crop Protection, Inc. P. O. Box 18300 Greensboro, NC 27419 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>100-902</u> Product Name <u>Emamectin Benzoate Technical</u>	

Section - II

- | | |
|--|--|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application. |
| <input type="checkbox"/> Notification - Explain below. | <input checked="" type="checkbox"/> Other - Explain below. |

Explanation: Use Additional Page(s) If Necessary. (For Section I And Section II.) Syngenta is submitting an application to register a new product, Emamectin Benzoate Technical II that is substantially similar to Emamectin Benzoate Technical, EPA Reg. No. 100-902. The submission includes acute toxicity, and certain product chemistry studies with Emamectin Benzoate Technical II, an acute oral & a mutagenicity study with certain impurities, and a rationale for substantial similarity classification of the 2 technicals. Syngenta is also referencing data on file with the EPA for Emamectin Benzoate Technical (100-902). The proposed label for Emamectin Benzoate Technical II will have the same uses as the uses that are approved for Emamectin Benzoate Technical. **PRIA Category R33 - New Product, Old AI, Selective citation** **Contact:** Carolyn Brinkley: carolyn.brinkley@syngenta.com

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) Refillable bulk bags		
*Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Unit Packaging wgt. No. per container		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 4,10,15, 25, 50, 100, 200, 500, 1000 lbs		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Other Enclosed in pocket or sleeve <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Carolyn F. Brinkley		Title Senior Regulatory Product Manager		Telephone No. (Include Area Code) (336) 632-2838	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature <i>Carolyn F. Brinkley</i>		3. Title Senior Regulatory Product Manager			
4. Typed Name Carolyn F. Brinkley		5. Date December 1, 2006			



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number
 Syngenta Crop Protection, Inc.

EPA Registration Number/File Symbol
 100-

Active Ingredient(s) and/or representative test compound(s)
 emamectin benzoate technical

Date
 December 1, 2006

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)
 terrestrial food use

Product Name
 Emamectin Benzoate Technical II

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Carolyn F. Brinkley

Date

Dec. 1, 2006

Typed or Printed Name and Title

Carolyn F. Brinkley, Sr. Regulatory Product Mgr.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 12/1/2006

Reg. No: 100-XXXX

Page 1 of 19

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
61 Series	Product identity and composition	42743644	MERCK & CO., INC.	PER	
61 Series	Product identity and composition	43824001	MERCK & CO., INC.	PER	
61 Series	Product identity and composition	45420801	SYNGENTA	OWN	
61-2	Certified limits	44883701	SYNGENTA	OWN	
61-3	Discussion of formation of impurities	43393010	MERCK & CO., INC.	PER	
62 Series	Analysis and certification of product Ingredients	42743645	MERCK & CO., INC.	PER	
62 Series	Analysis and certification of product Ingredients	45420801	SYNGENTA	OWN	
62-2	Certified limits	43824001	MERCK & CO., INC.	PER	
62-3	Analytical methods to verify certified limits	43824001	MERCK & CO., INC.	PER	
62-3	Analytical methods to verify certified limits	44007908	MERCK & CO., INC.	PER	
62-3	Analytical methods to verify certified limits	44007909	MERCK & CO., INC.	PER	
63 Series	Group B -- Physical/Chemical Properties	42743646	MERCK & CO., INC.	PER	

Carolyn Brinkley, Senior Regulatory Product Manager

Date: 12/1/2006



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 12/1/2006

Reg. No: 100-XXXX

Page 2 of 19

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
63 Series	Group B -- Physical/Chemical Properties	42743647	MERCK & CO., INC.	PER	
63 Series	Group B -- Physical/Chemical Properties	42743649	MERCK & CO., INC.	PER	
63 Series	Group B -- Physical/Chemical Properties	42743651	MERCK & CO., INC.	PER	
63 Series	Group B -- Physical/Chemical Properties	43824002	MERCK & CO., INC.	PER	
63 Series	Group B -- Physical/Chemical Properties	44883705	SYNGENTA	OWN	
63-10	Dissociation constants in water	42794202	MERCK & CO., INC.	PER	
63-11	Octanol/water partition coefficient	42794202	MERCK & CO., INC.	PER	
63-11	Octanol/water partition coefficient	44883703	SYNGENTA	OWN	
63-12	pH	44883702	SYNGENTA	OWN	
63-13	Stability to normal and elevated temperatures, metals,	42743648	MERCK & CO., INC.	PER	
63-13	Stability to normal and elevated temperatures, metals,	43850103	MERCK & CO., INC.	PER	
63-17	Storage stability	42743646	MERCK & CO., INC.	PER	

Carolyn Brinkley, Senior Regulatory Product Manager

Date: 12/1/2006



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 12/1/2006

Reg. No: 100-XXXX

Page 3 of 19

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
63-17	Storage stability	42743650	MERCK & CO., INC.	PER	
63-20	Corrosion characteristics	42743646	MERCK & CO., INC.	PER	
63-20	Corrosion characteristics	42743649	MERCK & CO., INC.	PER	
63-5	Melting Point	42794202	MERCK & CO., INC.	PER	
63-7	Density/relative density/bulk density	42794202	MERCK & CO., INC.	PER	
63-8	Water solubility	42794202	MERCK & CO., INC.	PER	
63-8	Water solubility	43850102	MERCK & CO., INC.	PER	
63-8	Water solubility	44883704	SYNGENTA	OWN	
63-9	Vapor Pressure	42794202	MERCK & CO., INC.	PER	
830.1550	Product identity and composition	45420801	SYNGENTA	OWN	
830.1550	Product identity and composition	46044901	SYNGENTA	OWN	
830.1600	Description of materials used to produce the product	45420801	SYNGENTA	OWN	

Carolyn Brinkley, Senior Regulatory Product Manager

Date: 12/1/2006



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 12/1/2006

Reg. No: 100-XXXX

Page 4 of 19

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
830.1620	Description of production process	45420801	SYNGENTA	OWN	
830.1670	Discussion of formation of impurities	45420801	SYNGENTA	OWN	
830.1700	Preliminary analysis	46044901	SYNGENTA	OWN	
830.1750	Certified limits	46044901	SYNGENTA	OWN	
830.1800	Enforcement analytical method	46044901	SYNGENTA	OWN	
141-1	Honey bee acute toxicity	42851530	MERCK & CO., INC.	PER	
71-1	Avian acute oral toxicity test	42743601	MERCK & CO., INC.	PER	
71-1	Avian acute oral toxicity test	42868905	MERCK & CO., INC.	PER	
71-2	Avian dietary toxicity test	42851527	MERCK & CO., INC.	PER	
71-2	Avian dietary toxicity test	42851528	MERCK & CO., INC.	PER	
71-4	Avian reproduction test	43850104	MERCK & CO., INC.	PER	
71-4	Avian reproduction test	43850105	MERCK & CO., INC.	PER	

Carolyn Brinkley, Senior Regulatory Product Manager

Date: 12/1/2006



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 12/1/2006

Reg. No: 100-XXXX

Page 5 of 19

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
71-4	Avian reproduction test	44007910	MERCK & CO., INC.	PER	
71-4	Avian reproduction test	44007911	MERCK & CO., INC.	PER	
72-1	Fish acute toxicity test, freshwater and marine	42743602	MERCK & CO., INC.	PER	
72-1	Fish acute toxicity test, freshwater and marine	42851529	MERCK & CO., INC.	PER	
72-1	Fish acute toxicity test, freshwater and marine	43850106	MERCK & CO., INC.	PER	
72-2	Aquatic invertebrate acute toxicity test, freshwater dap	42743603	MERCK & CO., INC.	PER	
72-2	Aquatic invertebrate acute toxicity test, freshwater dap	44007901	MERCK & CO., INC.	PER	
72-3	Oyster acute toxicity test (shell deposition)	43393001	MERCK & CO., INC.	PER	
72-3	Oyster acute toxicity test (shell deposition)	43393002	MERCK & CO., INC.	PER	
72-3	Oyster acute toxicity test (shell deposition)	43393003	MERCK & CO., INC.	PER	
72-3	Oyster acute toxicity test (shell deposition)	44007912	MERCK & CO., INC.	PER	
72-3	Oyster acute toxicity test (shell deposition)	44007913	MERCK & CO., INC.	PER	

Carolyn Brinkley, Senior Regulatory Product Manager

Date: 12/1/2006



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 12/1/2006

Reg. No: 100-XXXX

Page 6 of 19

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
72-3	Oyster acute toxicity test (shell deposition)	44007914	MERCK & CO., INC.	PER	
72-4	Fish early life stage and aquatic invertebrate life-cycle	43393004	MERCK & CO., INC.	PER	
72-4	Fish early life stage and aquatic invertebrate life-cycle	43850107	MERCK & CO., INC.	PER	
72-4	Fish early life stage and aquatic invertebrate life-cycle	44305601	MERCK & CO., INC.	PER	
72-4	Fish early life stage and aquatic invertebrate life-cycle	45833001	SYNGENTA	OWN	
72-6	Aquatic Organism Accumulation Study	43393005	MERCK & CO., INC.	PER	
81-1	Acute oral toxicity	42743605	MERCK & CO., INC.	PER	
81-1	Acute oral toxicity	42743612	MERCK & CO., INC.	PER	
81-1	Acute oral toxicity	42743613	MERCK & CO., INC.	PER	
81-1	Acute oral toxicity	42851502	MERCK & CO., INC.	PER	
81-1	Acute oral toxicity	42851518	MERCK & CO., INC.	PER	
81-1	Acute oral toxicity	42851519	MERCK & CO., INC.	PER	

Carolyn Brinkley, Senior Regulatory Product Manager

Date: 12/1/2006



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 12/1/2006

Reg. No: 100-XXXX

Page 7 of 19

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
81-1	Acute oral toxicity	43824003	MERCK & CO., INC.	PER	
81-1	Acute oral toxicity	44007915	MERCK & CO., INC.	PER	
81-2	Acute dermal toxicity	42743606	MERCK & CO., INC.	PER	
81-2	Acute dermal toxicity	43824004	MERCK & CO., INC.	PER	
81-2	Acute dermal toxicity	43869401	MERCK & CO., INC.	PER	
81-3	Acute inhalation toxicity	42743608	MERCK & CO., INC.	PER	
81-3	Acute inhalation toxicity	43868101	MERCK & CO., INC.	PER	
81-3	Acute inhalation toxicity	43868102	MERCK & CO., INC.	PER	
81-4	Acute eye irritation	42743615	MERCK & CO., INC.	PER	
81-4	Acute eye irritation	43824005	MERCK & CO., INC.	PER	
81-4	Acute eye irritation	43850112	MERCK & CO., INC.	PER	
81-5	Acute dermal irritation	42743607	MERCK & CO., INC.	PER	

Carolyn Brinkley, Senior Regulatory Product Manager

Date: 12/1/2006



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 12/1/2006

Reg. No: 100-XXXX

Page 8 of 19

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
81-5	Acute dermal irritation	42743616	MERCK & CO., INC.	PER	
81-6	Skin sensitization	42743609	MERCK & CO., INC.	PER	
81-6	Skin sensitization	42743610	MERCK & CO., INC.	PER	
81-6	Skin sensitization	42743617	MERCK & CO., INC.	PER	
81-7	Acute Delayed Neurotoxicity in the Hen	42743611	MERCK & CO., INC.	PER	
81-7	Acute Delayed Neurotoxicity in the Hen	42743614	MERCK & CO., INC.	PER	
81-7	Acute Delayed Neurotoxicity in the Hen	42743626	MERCK & CO., INC.	PER	
81-8	Toxicology (Neurotoxicity Screening Battery)	42743618	MERCK & CO., INC.	PER	
81-8	Toxicology (Neurotoxicity Screening Battery)	42743619	MERCK & CO., INC.	PER	
82-1	90-Day oral toxicity in rodents	42743620	MERCK & CO., INC.	PER	
82-1	90-Day oral toxicity in rodents	42743621	MERCK & CO., INC.	PER	
82-1	90-Day oral toxicity in rodents	42743622	MERCK & CO., INC.	PER	

Carolyn Brinkley, Senior Regulatory Product Manager

Date: 12/1/2006



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 12/1/2006

Reg. No: 100-XXXX

Page 9 of 19

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Eamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
82-1	90-Day oral toxicity in rodents	42743623	MERCK & CO., INC.	PER	
82-1	90-Day oral toxicity in rodents	42794201	MERCK & CO., INC.	PER	
82-1	90-Day oral toxicity in rodents	43868103	MERCK & CO., INC.	PER	
82-2	Repeated dose dermal toxicity - 90-day	42743625	MERCK & CO., INC.	PER	
82-2	Repeated dose dermal toxicity - 90-day	44007902	MERCK & CO., INC.	PER	
82-5	Acute and 28-day delayed neurotoxicity of organopho	42743627	MERCK & CO., INC.	PER	
82-7	Neurotoxicity screening battery	42743628	MERCK & CO., INC.	PER	
82-7	Neurotoxicity screening battery	42743629	MERCK & CO., INC.	PER	
82-7	Neurotoxicity screening battery	42743630	MERCK & CO., INC.	PER	
82-7	Neurotoxicity screening battery	42851503	MERCK & CO., INC.	PER	
82-7	Neurotoxicity screening battery	42851504	MERCK & CO., INC.	PER	
82-7	Neurotoxicity screening battery	42851505	MERCK & CO., INC.	PER	

Carolyn Brinkley, Senior Regulatory Product Manager

Date: 12/1/2006



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 12/1/2006

Reg. No: 100-XXXX

Page 10 of 19

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
82-7	Neurotoxicity screening battery	42851506	MERCK & CO., INC.	PER	
82-7	Neurotoxicity screening battery	42851507	MERCK & CO., INC.	PER	
82-7	Neurotoxicity screening battery	42851508	MERCK & CO., INC.	PER	
82-7	Neurotoxicity screening battery	42851509	MERCK & CO., INC.	PER	
83-1	Chronic toxicity	42743624	MERCK & CO., INC.	PER	
83-1	Chronic toxicity	42851510	MERCK & CO., INC.	PER	
83-1	Chronic toxicity	42868902	MERCK & CO., INC.	PER	
83-1	Chronic toxicity	43868104	MERCK & CO., INC.	PER	
83-2	Carcinogenicity	43868104	MERCK & CO., INC.	PER	
83-2	Carcinogenicity	43868105	MERCK & CO., INC.	PER	
83-3	Prenatal developmental toxicity study	42743631	MERCK & CO., INC.	PER	
83-3	Prenatal developmental toxicity study	42743632	MERCK & CO., INC.	PER	

Carolyn Brinkley, Senior Regulatory Product Manager

Date: 12/1/2006



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 12/1/2006

Reg. No: 100-XXXX

Page 11 of 19

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
83-3	Prenatal developmental toxicity study	42743634	MERCK & CO., INC.	PER	
83-3	Prenatal developmental toxicity study	42743635	MERCK & CO., INC.	PER	
83-3	Prenatal developmental toxicity study	42743636	MERCK & CO., INC.	PER	
83-4	Reproduction and Fertility Effects	42743633	MERCK & CO., INC.	PER	
83-4	Reproduction and Fertility Effects	42851511	MERCK & CO., INC.	PER	
84-2	Genetic Toxicity tests	42743637	MERCK & CO., INC.	PER	
84-2	Genetic Toxicity tests	42743638	MERCK & CO., INC.	PER	
84-2	Genetic Toxicity tests	42743639	MERCK & CO., INC.	PER	
84-2	Genetic Toxicity tests	42851512	MERCK & CO., INC.	PER	
84-2	Genetic Toxicity tests	42851513	MERCK & CO., INC.	PER	
84-2	Genetic Toxicity tests	42851514	MERCK & CO., INC.	PER	
84-2	Genetic Toxicity tests	42851515	MERCK & CO., INC.	PER	

Carolyn Brinkley, Senior Regulatory Product Manager

Date: 12/1/2006



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 12/1/2006

Reg. No: 100-XXXX

Page 12 of 19

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Eamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
84-2	Genetic Toxicity tests	42851516	MERCK & CO., INC.	PER	
84-2	Genetic Toxicity tests	42851517	MERCK & CO., INC.	PER	
85-1	Metabolism and Pharmacokinetics	42743640	MERCK & CO., INC.	PER	
85-1	Metabolism and Pharmacokinetics	42743641	MERCK & CO., INC.	PER	
85-1	Metabolism and Pharmacokinetics	44030601	MERCK & CO., INC.	PER	
85-3	Dermal Penetration	43850113	MERCK & CO., INC.	PER	
123-2	Aquatic plant toxicity test using Lemna spp. Tiers I an	43850108	MERCK & CO., INC.	PER	
123-2	Aquatic plant toxicity test using Lemna spp. Tiers I an	43850109	MERCK & CO., INC.	PER	
132-1	Foliar dislodgeable residue dissipation, Soil residue di	43850126	MERCK & CO., INC.	PER	
132-1	Foliar dislodgeable residue dissipation, Soil residue di	44007903	MERCK & CO., INC.	PER	
133-3	Dermal exposure	43850126	MERCK & CO., INC.	PER	
133-3	Dermal exposure	43943301	MERCK & CO., INC.	PER	

Carolyn Brinkley, Senior Regulatory Product Manager

Date: 12/1/2006



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 12/1/2006

Reg. No: 100-XXXX

Page 13 of 19

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Eamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
133-4	Inhalation Passive Dosimetry Exposure	43943301	MERCK & CO., INC.	PER	
141-2	Honey Bee Toxicity of Residues on Foliage	43393006	MERCK & CO., INC.	PER	
161-1	Hydrolysis - laboratory	42743642	MERCK & CO., INC.	PER	
161-2	Photodegradation in water - laboratory	43404301	MERCK & CO., INC.	PER	
161-2	Photodegradation in water - laboratory	43850114	MERCK & CO., INC.	PER	
161-3	Photodegradation in soil - laboratory	43404302	MERCK & CO., INC.	PER	
161-3	Photodegradation in soil - laboratory	44010001	MERCK & CO., INC.	PER	
161-4	Photodegradation in Air	44007906	MERCK & CO., INC.	PER	
161-4	Photodegradation in Air	44007907	MERCK & CO., INC.	PER	
162-1	Aeroic Soil metabolism	43235101	MERCK & CO., INC.	PER	
162-1	Aeroic Soil metabolism	43404303	MERCK & CO., INC.	PER	
162-1	Aeroic Soil metabolism	43850115	MERCK & CO., INC.	PER	

Carolyn Brinkley, Senior Regulatory Product Manager

Date: 12/1/2006



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 12/1/2006

Reg. No: 100-XXXX

Page 14 of 19

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
162-1	Aeroic Soil metabolism	44007905	MERCK & CO., INC.	PER	
162-1	Aeroic Soil metabolism	44010001	MERCK & CO., INC.	PER	
162-2	Anaerobic Soil Metabolism	43850116	MERCK & CO., INC.	PER	
163-1	Leaching and adsorption/desorption -- laboratory	42743643	MERCK & CO., INC.	PER	
163-1	Leaching and adsorption/desorption -- laboratory	43850117	MERCK & CO., INC.	PER	
164-1	Soil dissipation -- field	43404304	MERCK & CO., INC.	PER	
164-1	Soil dissipation -- field	43850118	MERCK & CO., INC.	PER	
165-1	Confined accumulation in rotational crops	43850119	MERCK & CO., INC.	PER	
171-11	Crop field trials	44715103	SYNGENTA	OWN	
171-4A1	Nature of the residue -- plants, livestock	44007904	MERCK & CO., INC.	PER	
171-4A2	Nature of the residue--plants, livestock	42851522	MERCK & CO., INC.	PER	
171-4A2	Nature of the residue--plants, livestock	43850121	MERCK & CO., INC.	PER	

Carolyn Brinkley, Senior Regulatory Product Manager

Date: 12/1/2006



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 12/1/2006

Reg. No: 100-XXXX

Page 15 of 19

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
171-4A2	Nature of the residue--plants, livestock	43850122	MERCK & CO., INC.	PER	
171-4A2	Nature of the residue--plants, livestock	44007906	MERCK & CO., INC.	PER	
171-4A2	Nature of the residue--plants, livestock	44007907	MERCK & CO., INC.	PER	
171-4A3	Nature of the residue -- plants, livestock	44300107	MERCK & CO., INC.	PER	
171-4A3	Nature of the residue -- plants, livestock	44883710	SYNGENTA	OWN	
171-4A3	Nature of the residue -- plants, livestock	44883711	SYNGENTA	OWN	
171-4A3	Nature of the residue -- plants, livestock	44883714	SYNGENTA	OWN	
171-4B	Nature of the residue -- plants, livestock	42868904	MERCK & CO., INC.	PER	
171-4B	Nature of the residue -- plants, livestock	43404307	MERCK & CO., INC.	PER	
171-4B	Nature of the residue -- plants, livestock	43850123	MERCK & CO., INC.	PER	
171-4B	Nature of the residue -- plants, livestock	43850124	MERCK & CO., INC.	PER	
171-4B	Nature of the residue -- plants, livestock	43850125	MERCK & CO., INC.	PER	

Carolyn Brinkley, Senior Regulatory Product Manager

Date: 12/1/2006



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 12/1/2006

Reg. No: 100-XXXX

Page 16 of 19

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
171-4B	Nature of the residue -- plants, livestock	44300102	MERCK & CO., INC.	PER	
171-4B	Nature of the residue -- plants, livestock	44313201	MERCK & CO., INC.	PER	
171-4B	Nature of the residue -- plants, livestock	44596301	SYNGENTA	OWN	
171-4B	Nature of the residue -- plants, livestock	44883712	SYNGENTA	OWN	
171-4B	Nature of the residue -- plants, livestock	44883713	SYNGENTA	OWN	
171-4B	Nature of the residue -- plants, livestock	45209801	SYNGENTA	OWN	
171-4C	Residue analytical method	42851520	MERCK & CO., INC.	PER	
171-4C	Residue analytical method	42851521	MERCK & CO., INC.	PER	
171-4C	Residue analytical method	42868903	MERCK & CO., INC.	PER	
171-4C	Residue analytical method	43393011	MERCK & CO., INC.	PER	
171-4C	Residue analytical method	43393012	MERCK & CO., INC.	PER	
171-4C	Residue analytical method	43415301	MERCK & CO., INC.	PER	

Carolyn Brinkley, Senior Regulatory Product Manager

Date: 12/1/2006



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 12/1/2006

Reg. No: 100-XXXX

Page 17 of 19

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
171-4C	Residue analytical method	43850121	MERCK & CO., INC.	PER	
171-4C	Residue analytical method	43850122	MERCK & CO., INC.	PER	
171-4C	Residue analytical method	44030602	MERCK & CO., INC.	PER	
171-4C	Residue analytical method	44300101	MERCK & CO., INC.	PER	
171-4C	Residue analytical method	44300103	MERCK & CO., INC.	PER	
171-4C	Residue analytical method	44300106	MERCK & CO., INC.	PER	
171-4C	Residue analytical method	44795001	SYNGENTA	OWN	
171-4C	Residue analytical method	44883707	SYNGENTA	OWN	
171-4C	Residue analytical method	44883708	SYNGENTA	OWN	
171-4C	Residue analytical method	44883709	SYNGENTA	OWN	
171-4C	Residue analytical method	44883715	SYNGENTA	OWN	
171-4C	Residue analytical method	44883716	SYNGENTA	OWN	

Carolyn Brinkley, Senior Regulatory Product Manager

Date: 12/1/2006



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 12/1/2006

Reg. No: 100-XXXX

Page 18 of 19

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Enamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
171-4C	Residue analytical method	45209802	SYNGENTA	OWN	
171-4C	Residue analytical method	45209803	SYNGENTA	OWN	
860.1000	Background	44715103	SYNGENTA	OWN	
860.1000	Background	46587001	SYNGENTA	OWN	
860.1000	Background	46587002	SYNGENTA	OWN	
860.1340	Residue analytical method	44596301	SYNGENTA	OWN	
860.1340	Residue analytical method	45209801	SYNGENTA	OWN	
860.1380	Storage stability data	46734701	SYNGENTA	OWN	
860.1500	Crop field trials	44715103	SYNGENTA	OWN	
860.1500	Crop field trials	45209802	SYNGENTA	OWN	
860.1500	Crop field trials	45209803	SYNGENTA	OWN	
860.1500	Crop field trials	46587001	SYNGENTA	OWN	

Carolyn Brinkley, Senior Regulatory Product Manager

Date: 12/1/2006



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 12/1/2006

Reg. No: 100-XXXX

Page 19 of 19

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
860.1500	Crop field trials	46587002	SYNGENTA	OWN	
860.1520	Processed food/feed	46587002	SYNGENTA	OWN	

Carolyn Brinkley, Senior Regulatory Product Manager

Date: 12/1/2006



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per session for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to : Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not sent the form to this address.

DATA MATRIX

Date : 12-05-06	EPA Reg No./File Symbol 100-XXXX	Page 1 of 3
Applicant's/Registrant's Name & Address Syngenta Crop Protection P.O. Box 18300 Greensboro, NC 27419-8300	Product: Enamectin Benzoate Technical II	
Ingredient Enamectin Benzoate Technical		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product identify and composition		SYNGENTA	OWN	
830.1620	Description of production process		SYNGENTA	OWN	
830.1670	Discussion of formation of impurities		SYNGENTA	OWN	
830.1700	Preliminary Analysis		SYNGENTA	OWN	
830.1750	Certified limits		SYNGENTA	OWN	
830.6302	Color		SYNGENTA	OWN	
830.6303	Physical state		SYNGENTA	OWN	
830.6304	Odor		SYNGENTA	OWN	
830.6313	Stability to normal and elevated		SYNGENTA	OWN	
830.6314	Oxidation/reduction chemical incompatibility		SYNGENTA	OWN	
830.6315	Flammability		SYNGENTA	OWN	
830.6316	Explodability		SYNGENTA	OWN	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per session for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to : Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not sent the form to this address.

DATA MATRIX

Date : 12-05-06	EPA Reg No./File Symbol 100-XXXX	Page 2 of 3
Applicant's/Registrant's Name & Address Syngenta Crop Protection P.O. Box 18300 Greensboro, NC 27419-8300	Product: Eamectin Benzoate Technical II	
Ingredient Eamectin Benzoate Technical		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6317	Storage stability		SYNGENTA	OWN	
830.6319	Miscibility		SYNGENTA	OWN	
830.6320	Corrosion characteristics		SYNGENTA	OWN	
830.6321	Dielectric breakdown voltage		SYNGENTA	OWN	
830.7000	pH		SYNGENTA	OWN	
830.7050	UV/Visible absorption		SYNGENTA	OWN	
830.7100	Viscosity		SYNGENTA	OWN	
830.7200	Melting point/melting range		SYNGENTA	OWN	
830.7220	Boiling point/boiling range		SYNGENTA	OWN	
830.7300	Density/relative density/bulk density		SYNGENTA	OWN	
830.7370	Dissociation constant in water		SYNGENTA	OWN	
830.7550	Partition coefficient (n-octanol/water), shake flask method		SYNGENTA	OWN	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per session for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to : Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not sent the form to this address.

DATA MATRIX

Date : 12-05-06	EPA Reg No./File Symbol 100-XXXX	Page 3 of 3
Applicant's/Registrant's Name & Address Syngenta Crop Protection P.O. Box 18300 Greensboro, NC 27419-8300	Product: Enamectin Benzoate Technical II	
Ingredient Enamectin Benzoate Technical		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7840	Water solubility Column elution method; shake flask		SYNGENTA	OWN	
870.1000	Acute toxicity testing-background		SYNGENTA	OWN	
870.1100	Acute oral toxicity		SYNGENTA	OWN	
870.1200	Acute dermal toxicity		SYNGENTA	OWN	
870.1300	Acute inhalation toxicity		SYNGENTA	OWN	
870.2400	Acute eye irritation		SYNGENTA	OWN	
870.2500	Acute dermal irritation		SYNGENTA	OWN	
870.2600	Skin sensitization		SYNGENTA	OWN	
870.5100	Bacterial reverse mutation test		SYNGENTA	OWN	
Signature <i>Carolyn F. Brinkley</i>			Name and Title Carolyn F. Brinkley, Senior Regulatory Product Manager		

Notice

The electronic copy of the label
(on a CD) submitted with this
application has been removed by
the In-processing Team for entry
into the Electronic Label Library*
(ELL)

☐ e-label NOT OK, rejected –
NOT posted to the ELL

*Lotus Notes Database

Contact Tom Harris, RD (308-9423) or Jim
Downing, ISB (308-9071) for further
information

Certification with Respect to Label Integrity

Version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
100-xxxxx	November 30, 2006	000100-xxxxx.20061130.china.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Carolyn Brinkley
Signature

November 30, 2006
Date

Carolyn F. Brinkley
Name (typed)

Sr. Regulatory Product
Manager
Insecticides
Title

Enamectin Benzoate Technical II

An insecticide for formulation into end-use insecticide products intended for non-domestic terrestrial outdoor food use.

Active Ingredient:

Enamectin Benzoate (CAS No. 155569-91-8) 97.0%

Other Ingredients: 3.0%

Total: 100.0%

KEEP OUT OF REACH OF CHILDREN

WARNING/AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use on label.

EPA Reg. No. 100-xxxx

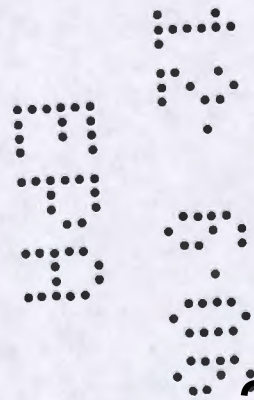
EPA Est. xxxxx

Product of China

Product ID.

SCP xxxxA(draft-China)

Net Contents



FIRST AID	
③ If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
① If swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person
④ If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
② If inhaled	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth, if possible.• Call a poison control center or doctor for treatment advice.
NOTE TO PHYSICIAN Probably mucosal damage may contraindicate the use of gastric lavage. Early signs of intoxication include dilated pupils, muscular incoordination, and muscle tremors. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements. In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since ivermectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic ivermectin benzoate exposure.	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
HOT LINE NUMBER For 24 Hour Medical Emergency Assistance (Human or Animal) or Chemical Emergency Assistance (Spill, Leak, Fire, or Accident), Call 1-800-888-8372	

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING/AVISO

May be fatal if inhaled or swallowed. Harmful if absorbed through skin. Causes moderate eye irritation.
Wear [respirator]
Causes substantial, but temporary, eye injury. Do not get in eyes or on clothing. *Wear OK*
~~protective eyewear (goggles, face shield, or safety glasses).~~ Harmful if swallowed, absorbed through the skin or inhaled. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.
Do not breathe dust. Avoid contact with skin, eyes, or clothing.

Environmental Hazards

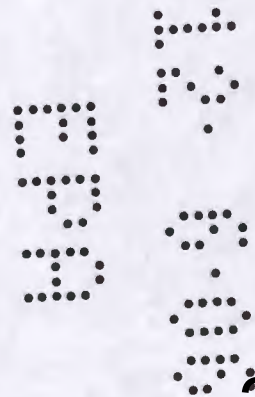
This pesticide is toxic to fish, birds, mammals, and aquatic invertebrates. Do not discharge effluent containing this active ingredient into lakes, streams, ponds, estuaries, oceans, or other public waters, unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit, and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

PPZ per 100-125g

*min = respirator - outline
eyewear*

Chem gloves -

Don't touch



CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

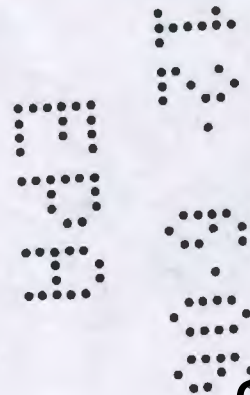
NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product ^{must} should be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Buyer is solely responsible for any risk created by the use or uses to with it or a User puts this product. SYNGENTA CROP PROTECTION, INC. shall not be responsible for any risk caused by the incorporation of this product into an end-use product by Buyer or User. All such risk shall be assumed by Buyer and user, and Buyer and User agree to hold SYNGENTA and Seller harmless fro any claims relating to such factors. SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use when used in accordance with directions under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and Buyer and User assume the risk of any such use. SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

Consistent of applicable law
IT IS SYNGENTA'S AND SELLER'S INTENTION THAT to the extent ~~allowable by~~ ^{to the extent allowable} ~~State law~~, SYNGENTA or the Seller shall not be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and of Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

*to the extent allowable
by state law
consistent of applicable law.*



DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Instructions to Formulators

Formulators using this product are responsible for obtaining Environmental Protection Agency registration for their formulated products.

This technical product may be used only for formulation of end-use insecticides for the uses listed below:

Agricultural crops (Terrestrial Food Crops)✓

- ✓ • *Brassica* leafy vegetables crop group 5
- ✓ • Cotton
- ✓ • Fruiting vegetables (except cucurbits) crop group 8
- ✓ • Leafy vegetables (except *Brassica*) crop group 5✓4
- ✓ • Pome fruit crop group 11
- Tobacco
- Turnip greens (tops, leaves)*

*For use on turnip varieties grown for leaves only. Do not use on turnip varieties grown for roots or dual-purpose varieties grown for roots and leaves.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage

Store in a tightly closed original container in a cool, dry place. Do not store near food or feed.

Pesticide Disposal

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal

Bulk

Thoroughly clean container before reuse. Consult Federal, state, or local disposal authorities for approved alternative procedures.

250 Gal. Mini Bulk

This is a refillable container that must be returned to an authorized Syngenta refilling facility for refilling or disposal. Before refilling, inspect thoroughly for damage such as cracks, punctures,

bulges, dents, abrasions, and damaged or worn threads on closure devices. After filling and before transporting, check for leaks. Do not refill or transport damaged or leaking container.

Other Containers

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

CONTAINER IS NOT SAFE FOR FOOD, FEED, OR DRINKING WATER.

Note: For minor spills, leaks, etc. follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during clean up and disposal of wastes.

The Syngenta logo is a trademark of a Syngenta Group Company.

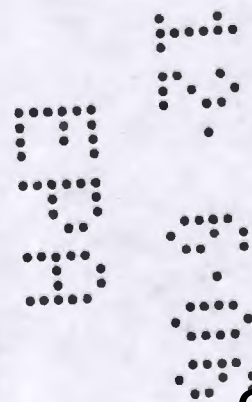
©2006 Syngenta

For non-emergency (e.g. current product information)
call Syngenta Crop Protection, Inc. at 1-800-334-9481

Manufactured for:
Syngenta Crop Protection, Inc.
Greensboro, North Carolina 27409
www.syngenta-us.com

SCP xxxxA(draft-China)

EmaBenzTech(draft-China)-lg-11-30-06 000100-xxxxx.20061130.china.pdf



Chron

November 29, 2006 – created label for initial registration of this product which will be produced in China – matches the uses on the label for Emamectin Benzoate Technical (EPA Reg. No. 100-902), however precautionary statements and signal word differ based on results of acute tox texts.

